A DISSERTATION ON

"A PROSPECTIVE STUDY ON THE CLINICAL OUTCOMES IN THE SURGICAL MANAGEMENT OF FAILED ERCP CHOLEDOCHOLITHIASIS – AN INSTITUTIONAL EXPERIENCE"

Dissertation submitted to

THE TAMIL NADU Dr. M. G. R. MEDICAL UNIVERSITY,

CHENNAI

with partial fulfilment of the regulations

for the Award of the degree

M.S. (General Surgery)

Branch –I

INSTITUTE OF GENERAL SURGERY,

MADRAS MEDICAL COLLEGE, CHENNAI.

MAY 2019.

CERTIFICATE

This is to certify that the dissertation titled "**A PROSPECTIVE STUDY ON THE CLINICAL OUTCOMES IN THE SURGICAL MANAGEMENT OF FAILED ERCP CHOLEDOCHOLITHIASIS – AN INSTITUTIONAL EXPERIENCE**" is the bonafide work of **Dr. P. V. SUDHARSAN** during his M.S. (General Surgery) programme between **2016 - 2019**, and was done under my supervision and is, herewith submitted in the partial fulfilment of **M.S. (BRANCH-I) - General Surgery, May 2019** examination of **The Tamil Nadu Dr. M. G. R. Medical University**.

Date:

Place: Chennai

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DECLARATION

I hereby, declare that this dissertation titled **"A PROSPECTIVE STUDY ON THE CLINICAL OUTCOMES IN THE SURGICAL MANAGEMENT OF FAILED ERCP CHOLEDOCHOLITHIASIS – AN INSTITUTIONAL EXPERIENCE"** represents a genuine work of mine. The contributions of any supervisors to the research are consistent with normal supervisory practice , and are acknowledged.

I also affirm that this bonafide work or part of this work was not submitted by me or any others for any award , degree or diploma to any other University board , either in India or abroad.

This is submitted to The Tamil Nadu Dr. M.G.R Medical University, Chennai in partial fulfillment of the rules and regulations for the award of Master of Surgery Degree Branch- I (General Surgery).

Date: 18-10-2018

Place: Chennai **Dr. P. V. SUDHARSAN**

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I, hereby declare that The Tamil Nadu Dr. M. G. R. Medical University shall have the right to preserve, use and disseminate this dissertation/thesis in print or electronic format for academic or research purpose.

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ACKNOWLEDGEMENT

“Research is to see what everybody else has seen, and to think what nobody else has thought.” - Albert Szent-Gyorgyi

I realize with a deep sense of humility and gratefulness that whatever little I have done now would not have been possible, but for certain mentors, who have enlightened my path to wisdom.

“Surgery is learnt by apprenticeship and not from textbooks, not even from one profusely illustrated ” - Ian Aird.

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With deep reverence, I thank my parents, my grandparents and my fiancée for their unflinching support and love. I thank Almighty for blessing me with a wonderful family to whom I have dedicated this thesis.

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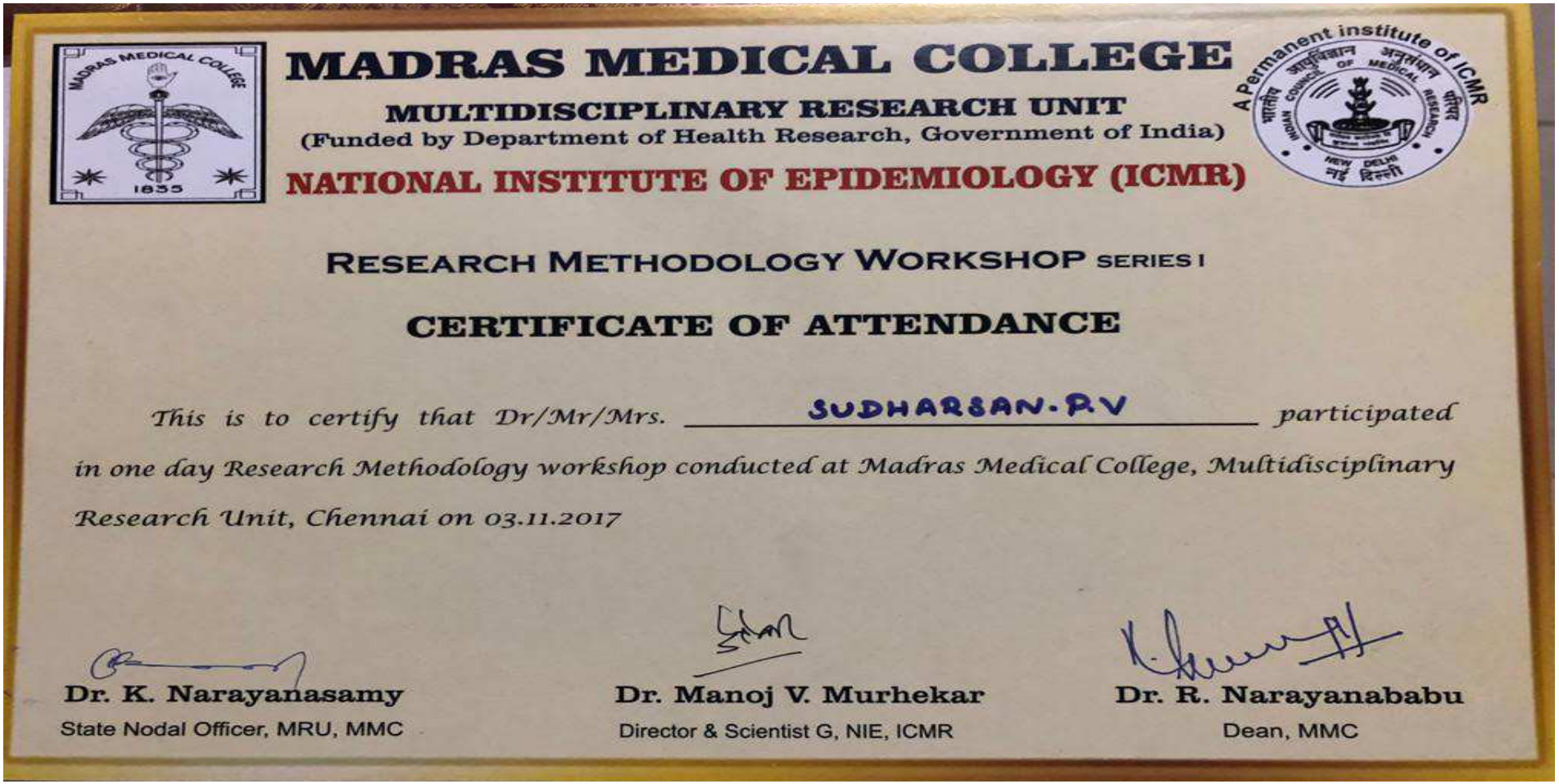

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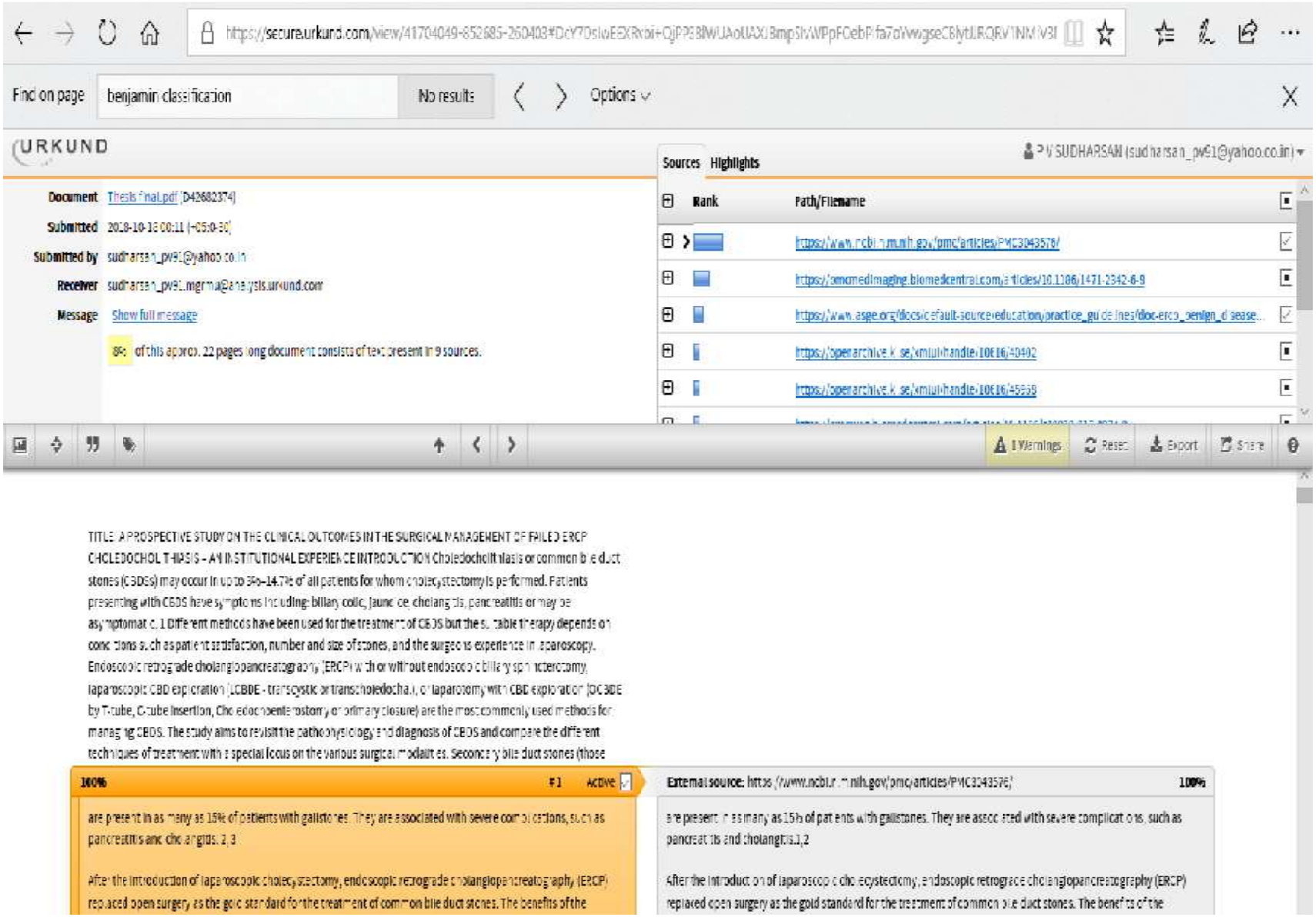
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TITLE: A PROSPECTIVE STUDY ON THE CLINICAL OUTCOMES IN THE SURGICAL MANAGEMENT OF FAILED ERCP CHOLEDOCHOLITHIASIS - AN INSTITUTIONAL EXPERIENCE INTRODUCTION Choledocholithiasis or common bile duct stones (CBDSs) may occur in up to 3%–14.7% of all patients for whom cholecystectomy is performed. Patients presenting with CBDS have symptoms including: biliary colic, jaundice, cholangitis, pancreatitis or may be asymptomatic. 1 Different methods have been used for the treatment of CBDS but the suitable therapy depends on conditions such as patient satisfaction, number and size of stones, and the surgeon's experience in laparoscopy. Endoscopic retrograde cholangiopancreatography (ERCP) with or without endoscopic biliary sphincterotomy, laparoscopic CBD exploration (LCBDE - transcystic or transcholedochal), or laparotomy with CBD exploration (OCBDE by T-tube, C-tube insertion, Choledochoenterostomy or primary closure) are the most commonly used methods for managing CBDS. The study aims to revisit the pathophysiology and diagnosis of CBDS and compare the different techniques of treatment with a special focus on the various surgical modalities. Secondary bile duct stones (those
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After the introduction of laparoscopic cholecystectomy, endoscopic retrograde cholangiopancreatography (ERCP) replaced open surgery as the gold standard for the treatment of common bile duct stones. The benefits of the
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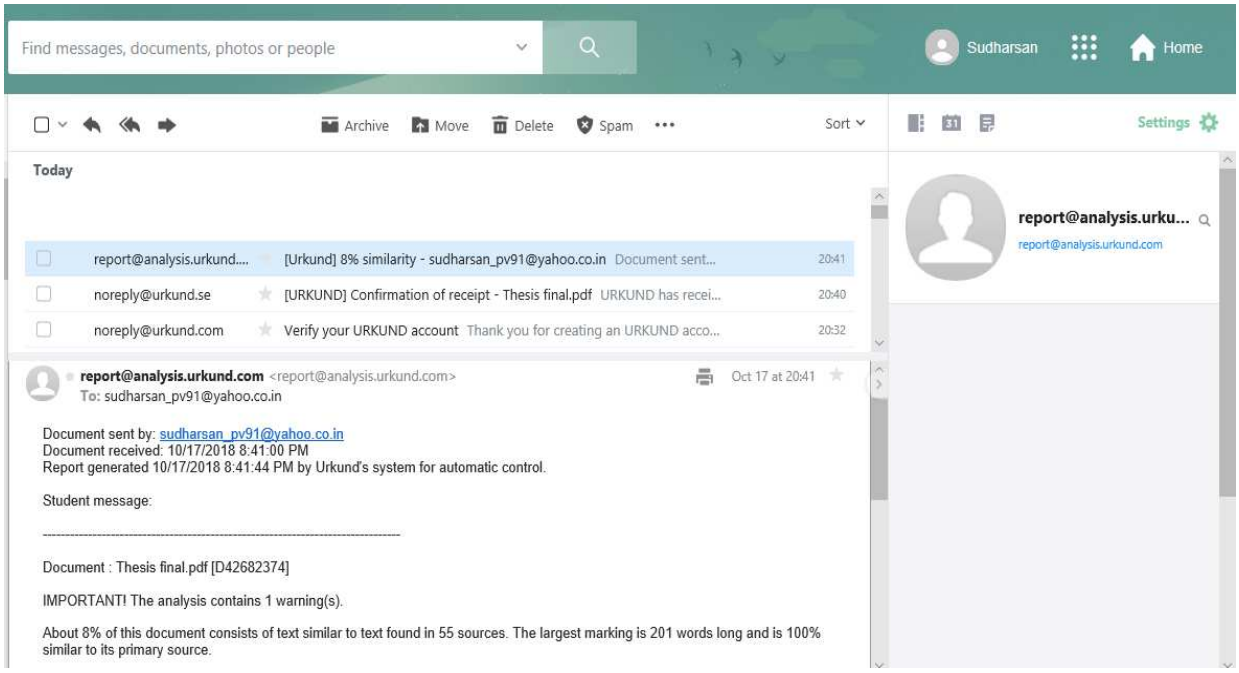
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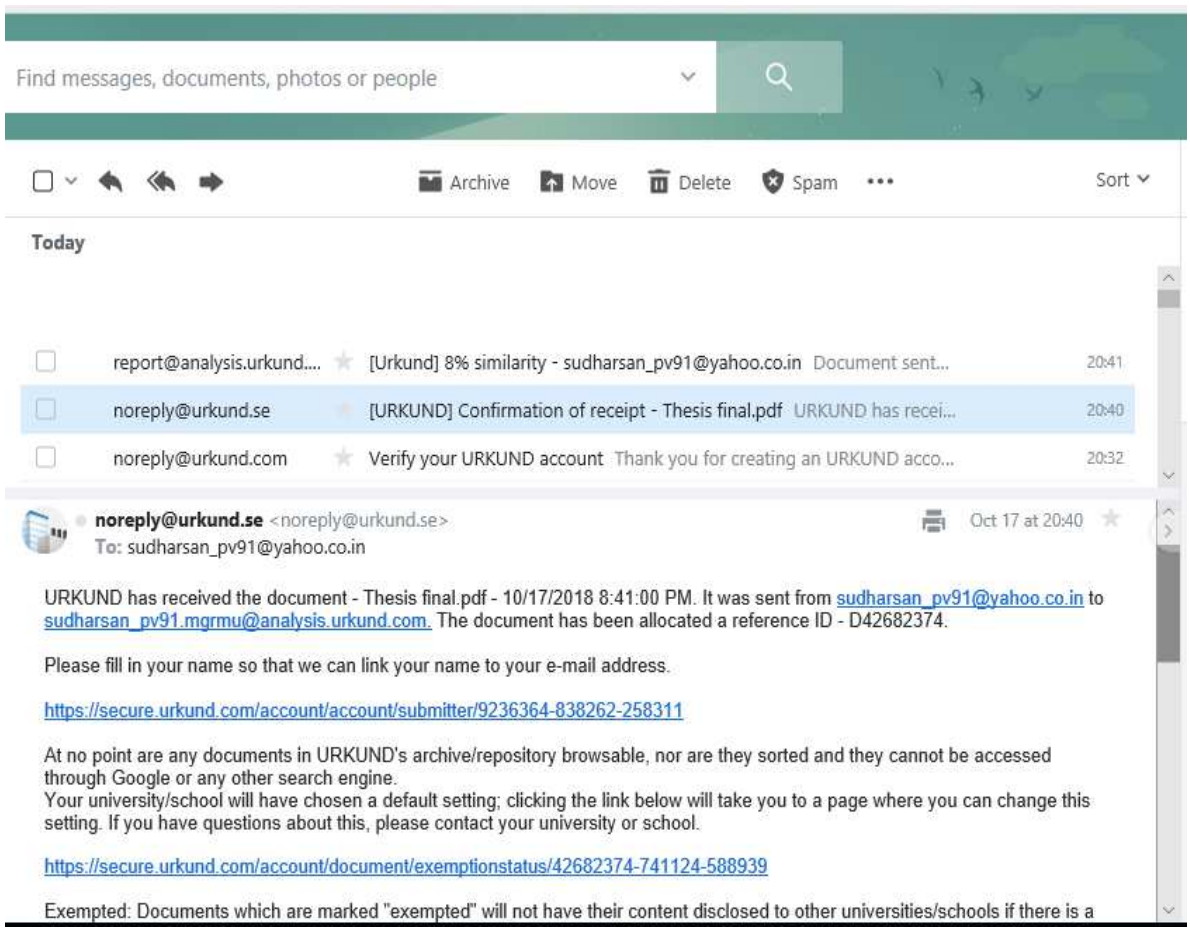
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TITLE: A PROSPECTIVE STUDY ON THE CLINICAL OUTCOMES IN THE SURGICAL MANAGEMENT OF FAILED ERCP CHOLEDOCHOLITHIASIS – AN INSTITUTIONAL EXPERIENCE

INTRODUCTION

Choledocholithiasis or common bile duct stones (CBDSs) may occur in up to 3%–14.7% of all patients for whom cholecystectomy is performed. Patients presenting with CBDS have symptoms including: biliary colic, jaundice, cholangitis, pancreatitis or may be asymptomatic.[1] Different methods have been used for the treatment of CBDS but the suitable therapy depends on conditions such as patient satisfaction, number and size of stones, and the surgeons experience in laparoscopy. Endoscopic retrograde cholangiopancreatography (ERCP) with or without endoscopic biliary sphincterotomy, laparoscopic CBD exploration (LCBDE - transcystic or transcholedochal), or laparotomy with CBD exploration (OCBDE by T-tube, C-tube insertion, Choledochoenterostomy or primary closure) are the most commonly used methods for managing CBDS. The study aims to revisit the pathophysiology and diagnosis of CBDS and compare the different techniques of treatment with a special focus on the various surgical modalities.

Secondary bile duct stones (those which arise from the gall bladder) are present in as many as 15% of patients with gallstones. They are associated with severe complications, such as pancreatitis and cholangitis. [2, 3]

After the introduction of laparoscopic cholecystectomy, endoscopic retrograde cholangiopancreatography (ERCP) replaced open surgery as the gold standard for the treatment of common bile duct stones. The benefits of the preoperative endoscopic treatment (ERCP) followed by LC (2-step approach) are substantially better compared with open surgery, regarding postoperative pain, hospital stay, return to work, and cosmesis.[4, 5]

However, ERCP has some issues, such as procedure-related complications and failed ERCP with a rate as high as 10% to 25%.[6] The limitations of endoscopic treatment are related to the complexity of doing a correct cannulation of the ampulla of Vater and stone retrieval. Patients with failed ERCP are considered high-complex cases.[6, 7]

The failure in retrieving bile duct stones by using ERCP is an absolute indication for performing CBDE. Once the laparoscopic surgeons have gained experience with laparoscopic cholecystectomy, minimally invasive surgery moved one step forward, to LCBDE. Since the first experiences reported in 1991,[11-13] this procedure has been done together with new technologies, currently considered as effective as ERCP. Some reports support the 1-step approach over the 2-step approach in terms of costs and hospital stay, as discussed below in the review of literature.

Thus, the identification of characteristics of CBD stones, which make them prone to failure by standardised ERCP extraction will go a long way in preventing the morbidity associated with failed ERCPs. This would allow the surgeon to enter the management of difficult CBD stones at an earlier stage and offer a primary, single-

step surgical solution to this complex problem. It would prevent unnecessary and/or repetitive ERC intervention in complex CBD pathology, and subsequently reduce the length of hospital stay, hospitalisation costs, complications, number of Quality Adjusted Life Years (QALYs) lost.

The standard protocol for managing a case of CBD stone disease in our tertiary care institute is as given in the flow chart below:

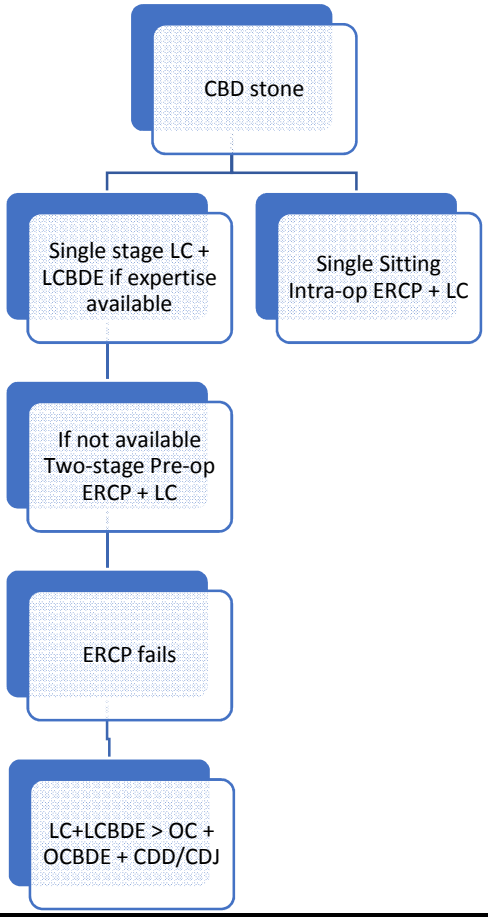

Fig. 1. Flow chart showing the management pathway for a Choledocholithiasis patient at our tertiary care institute. (Adapted from SAGES – Society of American Gastrointestinal and Endoscopic Surgeons)

AIMS AND OBJECTIVES

The primary research question taken up in the study was: What are the clinical, radiological and biochemical characteristics of CBD stones, that make them prone to ERCP failure?

And Question Two was: Is there a difference in clinical outcomes between the OCBDE + T and OCBDE + CDD/CDJ and LCBDE groups?

1. To compare outcome parameters for good-risk patients with classic signs, symptoms, and laboratory and abdominal imaging features of cholecystolithiasis and/or choledocholithiasis, failed to be treated by ERCP between 3 groups of patients:
    a. open cholecystectomy plus common bile duct exploration with primary closure or T-tube placement **(OC+OCBD+/-T);**
    b. Open cholecystectomy plus common bile duct exploration with choledochoduodenostomy/ jejunostomy/ Hepatico-jejunostomy **(OC+OCBDE+CD/CJ/HJ);**
    c. Laparoscopic cholecystectomy plus laparoscopic common bile duct exploration **(LC+LCBDE).**
2. To define clinical, radiological and biochemical characteristics of CBD stones prone for ERCP failure

REVIEW OF LITERATURE

1. CBD stones are one of the medical conditions leading to surgical intervention. They may occur in 3%–14.7% of all patients for whom cholecystectomies are performed.

    - Schirmer B, Winters KL, Edlich RF. Cholelithiasis and cholecystitis. *Journal of Long-Term Effects of Medical Implants*. 2005;15(3):329–338.

2. When patients present with CBD, the one important question that should be answered: what is the best modality of treatment under the giving conditions? There are competing technologies and approaches for diagnosing CBDS with regard to diagnostic performance characteristics, technical success, safety, and cost effectiveness.

    - Riciardi R, Islam S, Canete JJ, Arcand PL, Stoker ME. Effectiveness and long-term results of laparoscopic common bile duct exploration. *Surgical Endoscopy*. 2003;17(1):19–22.

3. It may be prudent to consider ERCP failure patients for primary LCBDE than risk the complications of ERCP if they are suitable for primary surgery.

    - Misra MC Outcomes of Laparoscopic Common Bile Duct Exploration After Failed Endoscopic Retrograde Cholangiopancreatography in Patients with Concomitant Gall Stones and Common Bile Duct Stones: A Prospective Study; *J Laparoendosc Adv Surg Tech A.*

4. CBDS usually requires two separate teams: the gastroenterologist and the surgical team. The main options for treatment are pre- or postoperative ERCP with endoscopic biliary sphincterotomy (EST), laparoscopic or open surgical bile duct clearance. It is unlikely that one option will be appropriate for all clinical circumstances in all centers. Variables such as disease status, patient demographics, availability of endoscopic, radiological and surgical expertise, and healthcare economics will all have significant influence on practice.

    - Carr-Locke DL. Cholelithiasis plus choledocholithiasis: ERCP first, what next? *Gastroenterology*. 2006;130(1):270–272.

5. LCBDE (trans-cystic or trans-ductal) is a standard method with a high efficacy and low morbidity and mortality for the treatment of CBDS in most centers. Pre- or postoperative ERCP/EST can be use as an alternative method. We recommend that for patients with CBDS, ERCP should be performed as a first step and in the event of failure LCBDE can be performed. It should not be forgot that the open approach always remains as a final option when others modalities have failed.

    - Abolfazl Shojaiefard, Majid Esmaeilzadeh, Ali Ghafouri, and Arianeb Mehrabi Various Techniques for the Surgical Treatment of Common Bile Duct Stones: A Meta Review; *Gastroenterol Res Pract.* 2009; Published online 2009 Aug 6.

6. *Choledocoenterostomy* is the most commonly performed as a side-to-side choledochoduodenostomy, usually in the setting of a dilated CBD with multiple stones, a recurrence of CBDS in the Vater's papilla occurred after ES

and dilated CBD (≥2.0 cm). These patients require drainage for good long-term results without recurrence of jaundice or cholangitis.

- Lacitignola S, Minardi M. Management of common bile duct stones: a ten-year experience at a tertiary care center. *Journal of the Society of Laparoendoscopic Surgeons*. 2008;12(1):62–65.

7. Both ERCP/S+LC and LC+LCBDE were highly effective in detecting and removing common bile duct stones and were equivalent in overall cost and patient acceptance. However, the overall duration of hospitalization was shorter and physician fees lower for LC+LCBDE.

    - Rogers SJ, Cello JP, Horn JK, Siperstein AE, Schecter WP, Campbell AR, Mackersie RC, Rodas A, Kreuwel HT, Harris HW. Prospective randomized trial of LC+LCBDE vs ERCP/S+LC for common bile duct stone disease. *Arch Surg. 2010* Jan;145(1):28-33. doi: 10.1001/archsurg.2009.226.

8. When LCBDS and postoperative ERCP have failed, the surgeon must use the open approach to surgery. Martin et al. reported open surgery as being more successful and being lower mortality than ERCP in CBDS.

    - Martin DJ, Vernon DR, Toouli J. Surgical versus endoscopic treatment of bile duct stones. *Cochrane Database of Systematic Reviews*. 2006;(2)

9. The current study suggests that LC+IO-ERCP for the management of cholecysto-choledocholithiasis is a safe and an effective technique with a low rate of post-ERCP pancreatitis. It offers another alternative for surgeons especially those who do not practice LCBDE to treat patients in a single setting.

    - Ghazal AH, Sorour MA, El-Riwini M, El-Bahrawy H. Single-step treatment of gall bladder and bile duct stones: a combined endoscopic-laparoscopic technique. *Int J Surg.* 2009 Aug;7(4):338-46. doi: 10.1016/j.ijsu.2009.05.005. Epub 2009 May

10. For patients undergoing laparoscopic surgery, we recommend laparoscopic transcystic exploration of the CBD as the initial surgical approach for patients with stones smaller than 10 mm and a small bile duct (Grade 1C). Choledochotomy should be reserved for patients in whom the duct cannot be cleared using a transcystic approach. Surgeons performing laparoscopic cholecystectomy should be prepared to convert to open CBD exploration if necessary.

    - W Scott Melvin, MD Peter Muscarella, MD, Common bile duct exploration, *UpToDate, Nov 05, 2012*

11. RADIOLOGICAL INVESTIGATIONS USED IN EVALUATION OF BILIARY TREE PATHOLOGY [15]:

Non-invasive:

1. **Ultrasonography**: Is the initial imaging modality of choice – accurate, easily available, inexpensive and quick.
    a. Shows biliary calculi,
    b. size of GB, thickness of GB wall,
    c. presence of peri-cholecystic inflammation,
    d. Extra-hepatic biliary dilatation,
    e. Level of obstruction.
    f. Free fluid – abdomen, liver mets

    ENDOSCOPIC USG: Endoscope with US transducer at its tip.

        a. Visualises Liver and biliary tree from within stomach and duodenum,
        b. Highly effective in diagnosing Choledocholithiasis,
        c. Diagnosing and Staging Periampullary CA and pancreatic CA.

2. Radiological Investigations of historical importance – **Oral Cholecystograhy and IV Cholangiography (Descending), Plain Radiograph** - may identify the 10 % of radio-opaque gall stones. Mercedes-Benz (triradiate fissure) or seagull sign (biradiate) is appreciated due to radiolucent gas in the gall stone.

3. **Computerised tomography:**
    a. For detecting hepatic and pancreatic lesions;
    b. Staging CA of liver, GB, bile duct and pancreas;
    c. Identifies metastasis and enlarged LN;
    d. ***Not*** useful in benign diseases, particularly cholecystitis and gallstones.

MDCT with 3D reconstruction of biliary tree increase diagnostic accuracy.

4. **Magnetic Resonance Cholangiopancreaticography:**
    a. Non-invasive compared to Percutaneous transhepatic cholangiography (PTC), ERCP;
    b. Contrast ***NOT*** required;
    c. Excellent cross-sectional and projection images possible;
    d. Same quality as ERCP and PTC.

Magnetic resonance cholangiopancreatography (MRCP) is an alternative to diagnostic endoscopic retrograde cholangiopancreatography (ERCP) for investigating biliary obstruction.

The use of MRCP, a non-invasive procedure, may prevent the use of unnecessary invasive procedures.[31]

Indications for the use of MRCP include:

- unsuccessful or contraindicated ERCP;
- patient preference for non-invasive imaging;
- patients considered to be at low risk of having pancreatic or biliary disease;
- patients where the need for therapeutic ERCP is considered unlikely;
- those with a suspected neoplastic cause for pancreatic or biliary obstruction;
- And suspicion of endoluminal common bile duct pathology.

No patient preparation is required for MRCP and sedation is not usually required. **MRCP is particularly useful where ERCP is difficult, hazardous or impossible. It is also an important option for patients with failed ERCPs.**

ERCP and MRCP have different contraindications allowing them to be used as complementary techniques.

MRCP is a comparable diagnostic investigation in comparison to ERCP for diagnosing biliary abnormalities, particularly favourable for choledocholethiasis and less so for malignancy.

The use of MRCP in suitable patients reduces the need for diagnostic ERCP which is associated with significant morbidity and mortality.

Fig. 2: MRCP of a patient in the study showing choledocholithiasis with dilated Intra-hepatic Biliary Radicles, and distended Gall Bladder.

5. RADIO-ISOTOPE SCANNING/CHOLE-/HEPATO-BILIARY SCINTIGRAPHY:

a. 99-m Tc = labelled derivatives of iminodiacetic acid (HIDA, IODIDA, PIPIDA) when injected IV, are actively taken up by the retro-endothelial cells of the liver, selectively, and excreted into bile.
b. This allows visualisation of GB and biliary tree.
c. The GB is visualised in 30 mins in 90 % of normal individuals and in 1 hr in the remainder 10 %.
d. Non- visualisation of the GB even after 4 hrs of injecting the agent is indicative of *acute cholecystitis.* It is the investigation of choice for identifying acute cholecystitis, especially when combined with USG.
e. Biliary Scintigraphy *identifies bile leaks and iatrogenic obstruction* following cholecystectomy.

Invasive:

1. ERCP (Endoscopic Retrograde Cholangio-pancreaticography):

Endoscopic retrograde cholangiopancreatography (ERCP) is a invasive technique that uses a combination of luminal endoscopy and fluoroscopic imaging, usually obtained with the help of a C-arm to diagnose and treat conditions associated with the pancreatobiliary system.

The endoscopic portion of the examination uses a side-viewing duodenoscope that is passed through the esophagus and stomach and into the second portion of the duodenum. The major duodenal papilla is identified by the side viewing scope and cannulated, so that a dye may be injected into the pancreatico-biliary system. The injected dye is then visualized by a fluoroscopic technique.

It remains the gold standard in diagnosing biliary tree pathology;

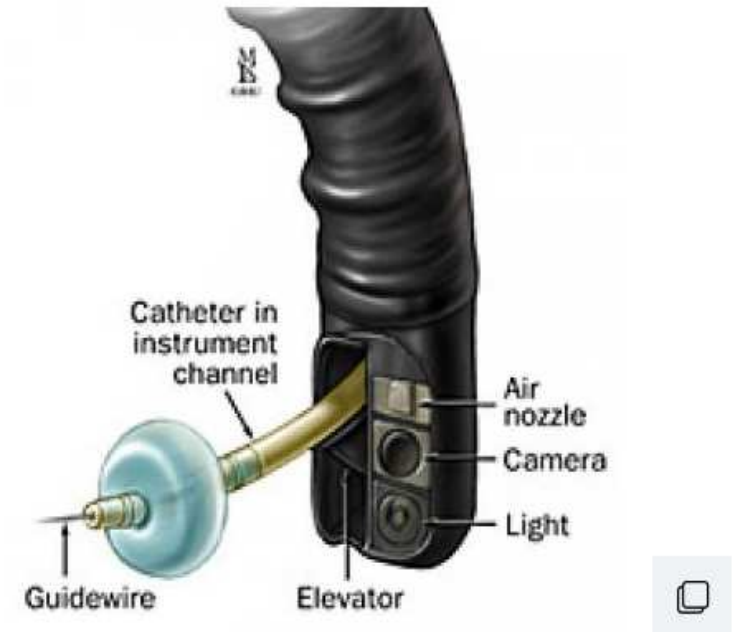

Fig. 3: A side viewing scope

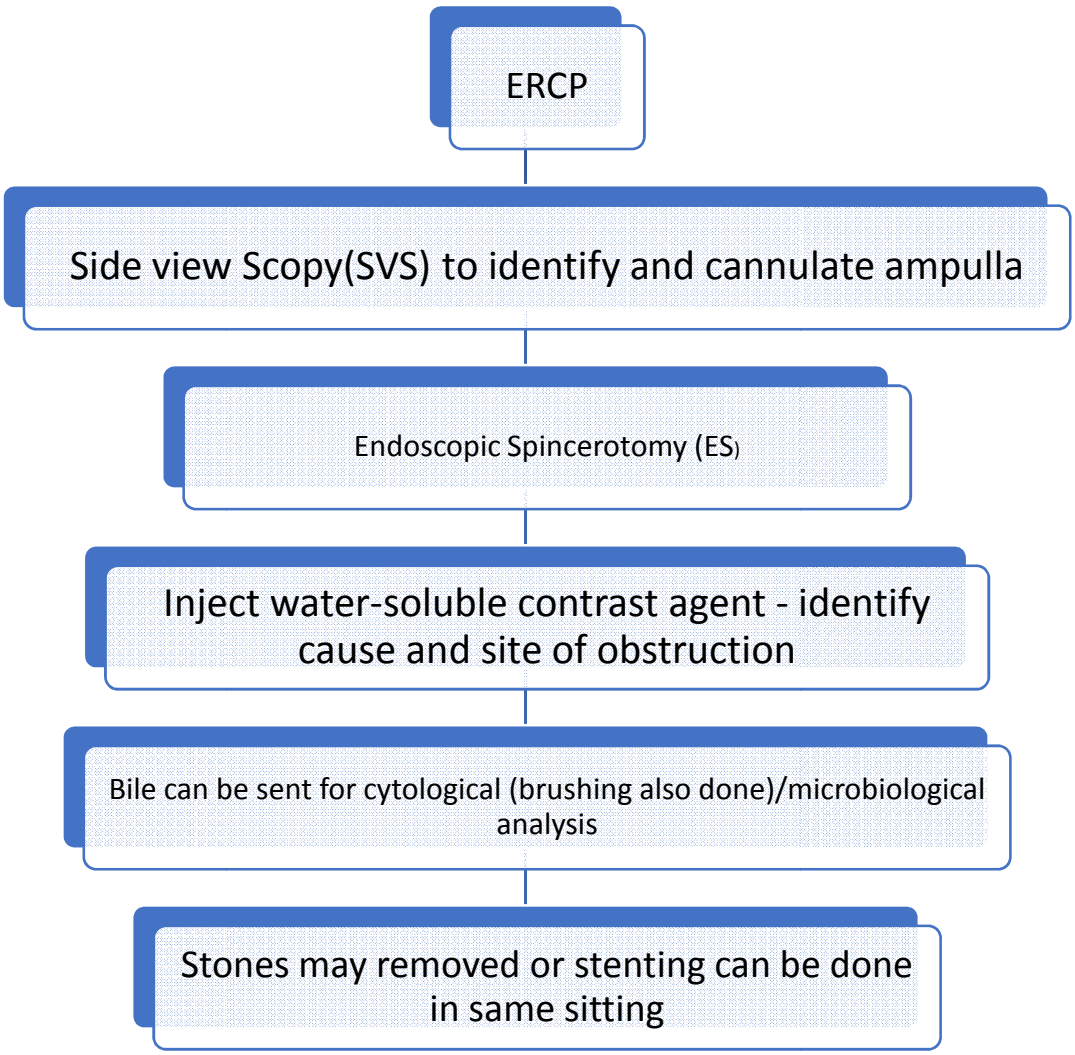

Fig. 4: ERCP Technique

Freeman et al, using data from 2004, estimated that about 500,000 procedures were performed annually in the United States.

However, because of a decrease in diagnostic ERCP with the advent of endoscopic ultrasonography (EUS) and magnetic resonance cholangiopancreatography (MRCP), this number is likely decreasing, and ERCP is

increasingly being performed purely for therapeutic purposes, particularly stone retrieval.

In 2005, the American Society for Gastrointestinal Endoscopy (ASGE) published guidelines regarding the role of ERCP in biliary tract and pancreatic diseases.

The guidelines were updated in 2015 to include the following recommendations for benign biliary tract disease:

- Diagnostic ERCP should **not be undertaken** to evaluate pancreaticobiliary-type pain in the absence of objective abnormalities on other pancreaticobiliary imaging or laboratory studies (moderate-quality evidence);
- **Routine ERCP before laparoscopic cholecystectomy is contraindicated** if there are no objective signs of biliary obstruction or stone (moderate-quality evidence);
- In patients with acute biliary pancreatitis, ERCP should be reserved for those with concomitant cholangitis or biliary obstruction (high-quality evidence);
- ERCP with dilation and stent placement is recommended for benign biliary strictures (moderate-quality evidence) ;
- ERCP should be performed as first-line therapy for postoperative biliary leakage (high-quality evidence);
- Cholangioscopy should be considered as an adjunct in the management of difficult bile duct stones that are not amenable to removal after sphincterotomy with or without balloon dilation or mechanical lithotripsy (low-quality evidence);

- Cholangioscopy with directed biopsy should be considered as an adjunct for characterizing biliary strictures (low-quality evidence);
- ERCP with sphincterotomy is recommended for patients with type I sphincter of Oddi dysfunction (SOD; moderate-quality evidence) ;
- ERCP is not recommended for evaluation or treatment of type III SOD (high-quality evidence) ;
- Rectal indomethacin with or without pancreatic stenting is recommended for prophylaxis against post-ERCP pancreatitis (PEP) when ERCP is performed in the setting of suspected SOD (moderate-quality evidence) ;

Absolute contraindications for ERCP include the following:

- Patient refusal to undergo the procedure
- Unstable cardiopulmonary, neurologic, or cardiovascular status
- Existing bowel perforation

Structural abnormalities of the esophagus, stomach, or small intestine may be relative contraindications for ERCP.

Examples are acquired conditions such as:

a) esophageal stricture,
b) paraesophageal herniation,
c) esophageal diverticulum,
d) gastric volvulus,
e) gastric outlet obstruction,
f) Choledochoduodenal fistula,
g) and small-bowel obstruction.

An altered surgical anatomy, such as is seen after partial gastrectomy with Billroth II or Roux-en-Y jejunostomy, may also be a relative contraindication for ERCP, especially when planning access to the bile duct system for stone retrieval.

Several factors play a role in choosing the best approach for ERCP access in patients with altered surgical anatomy in cases where ERCP is indeed indicated. These factors include:

a) long versus short Roux limb,

b) native papilla versus bilioenteric anastomosis,

c) prior sphincterotomy,

d) anticipated accessory use (eg, sphincter of Oddi manometry),

e) surgical risk,

f) likelihood of repeat procedures, and,

g) possibility of internal hernias.

The different approaches in patients with Roux-en-Y anatomy include duodenoscope through the anatomic route, colonoscope or enteroscope through the anatomic route, single/double balloon enteroscopes, spiral/rotational enteroscope, ERCP through gastrostomy or jejunostomy, laparoscopically assisted ERCP, or biliary access obtained by interventional radiology. However, their use for stone retrieval, especially of difficult choledocholithiasis is still under investigation.

Other relative contraindications include:

The presence of **acute pancreatitis** is typically considered a relative contraindication as well, **unless the etiology of the pancreatitis is gallstone-related** and the therapeutic goal is to improve the clinical course by means of stone extraction.

In addition, ERCP with sphincterotomy or ampullectomy is relatively contraindicated in **coagulopathic patients** (international normalized ratio [INR] >1.5 or platelet count <50,000/µL).

COMPLICATIONS ASSOCIATED WITH ERCP:

Because of inherent bias and patient underreporting, an accurate estimate of the procedural complication rate is difficult to obtain.

However, comparisons with complication data pertaining to other endoscopic procedures makes it clear that **ERCP is associated with approximately *four-fold* higher rates of severe complications.**

In a study of post-ERCP complications that pooled prospective patient survey data from almost 17,000 patients undergoing the procedure:

- ERCP-related morbidity secondary to pancreatitis, bleeding, perforations, and infections was 6.85%, of which 5.17% was graded as mild-to-moderate and 1.67% as severe; ERCP-specific mortality was 0.33%.
- Pancreatitis was the most common complication (3.47% of patients), followed by infection (1.44%), bleeding (1.34%), and perforations (0.6%).

The incidence of Post-ERCP pancreatitis ranges from 1% to 10% in average-risk patients but can exceed 25-30% in certain high-risk patient populations. This wide range is due to the heterogenous interplay of multiple patient-, procedure-, and operator-related factors.

Acute Post ERCP Pancreatitis is not a uniform disorder and varies in intensity. Most cases are mild and resolve with proper treatment without any permanent sequelae.

The relatively high risk associated with ERCP underscores the importance of having this procedure performed by experienced practitioners. It also helps explain the trend toward therapeutic as opposed to diagnostic ERCP. Although the absolute complication risk is greater with therapeutic ERCP than with diagnostic ERCP, **the potential benefits are also greater, and the risk-to-benefit ratio favors therapeutic ERCP.**

2. Percutaneous Transhepatic Cholangiography:

Absolute contraindications: Bleeding diathesis.

Prophylactic antibiotics is indicated. Under fluoroscopic control, Chiba/Okuda needle is introduced into the liver parenchyma, and a bile duct is cannulated under US/CT control. Water-soluble contrast is injected and images are taken to identify strictures/obstruction in the biliary tree.

Uses of Percutaneous Transhepatic Cholangiography:

1. External biliary drainage by placing catheter and decompress the biliary system;
2. Biopsies can be taken;
3. Intra-hepatic (Hepatolithiasis)/ Proximal CBD Stones can be removed;
4. Stenting can be done;
5. Choledochoscopy can be performed.

3. Per-operative cholangiography:

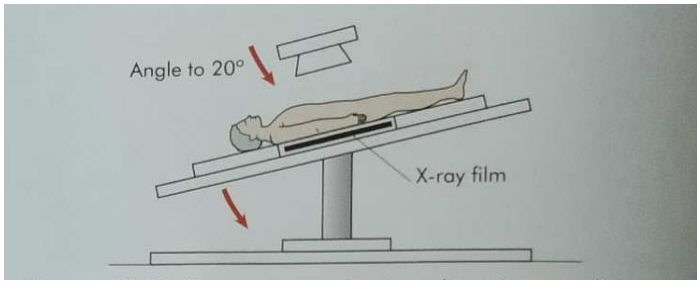

Fig 5: Positioning of patient during an intra-operative cholangiogram

The primary methods for assessing the common bile duct for stones or injury during cholecystectomy are intraoperative cholangiogram and intraoperative ultrasound.

Intraoperative cholangiography has been used for many years; fluoroscopy saves time and has improved its usefulness.

The issue of *routine verses selective* cholangiography has been long debated. *Studies have suggested routine use of intraoperative cholangiography may decrease the risk of injury and improve injury recognition while others have suggested cholecystectomy may be performed without cholangiogram with low rates of injury*. In addition, the skills developed and maintained by routine cholangiography provide a platform for progression to transcystic clearing or stenting of the common bile duct; in many cases clearing can be accomplished with simple measures such as administration of glucagon and flushing with saline. In terms of detecting bile duct stones, 2-12% of patients will have choledocholithiasis on routine intraoperative cholangiogram, and recent studies suggest as many as 10% of these are unsuspected prior to operation. A meta-analysis performed in 2004, revealed that the incidence of unsuspected retained stones was 4% with only 15% of these going on to cause clinical problems. **The conclusion from that study was that a selective policy should be advocated, though creating a reliable algorithm for predicting the presence of stones and thus the need for selective cholangiogram has been unsuccessful.**

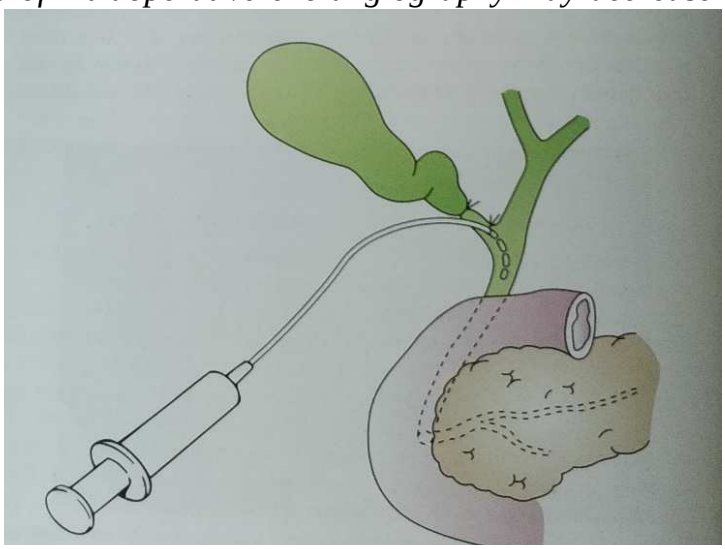

Fig.6: Intra-operative Cholangiogram

4. Operative Biliary endoscopy = Choledochoscopy:

Intra-operatively, flexible fibro-optic endoscope is passed down via the cystic duct in the CBD, to visualise any stones and remove them under direct vision. It is usually combined with intra-op X Ray imaging.

A T-Tube may be left post-op to allow a tract form, and post-op choledochoscopy can be performed after 7 – 10 days for removal of any residual stones. It is invaluable in the management of difficult CBD calculi.

12. MANAGEMENT OF CHOLEDOCHOLITHIAIS, ITS DIFFERENTIAL DIAGNOSIS AND SURGICAL TREATMENT OPTIONS:

A patient is diagnosed with surgical obstructive jaundice (SOJ) with a combination of clinical, biochemical and radiological evidence and suspicion.

Patients with surgical obstructive jaundice usually present with painless or painful, progressive or non-progressive jaundice. The classical history points to be noted in a case of surgical obstructive jaundice include the presence of itching (possibly as a presenting symptom), yellowish discoloration of urine and pale stools. History of malena may also be present. Loss of weight and appetite is noted in malignant causes of surgical obstructive jaundice.

Vomiting and dyspepsia are associated symptoms in surgical obstructive jaundice due to benign causes, particularly stone disease.

Benjamin et al in 1983, classified obstructive jaundice clinically based on the nature of obstruction into:

1. **Type I: Complete obstruction:**
    a. Tumors;
    b. Ligation/Clipping of CBD (Iatrogenic);
    c. Cholangiocarcinoma
2. **Type II: Intermittent obstruction:**
    a. Choledocholithiasis;
    b. Periampullary CA;
    c. Duodenal diverticulae;
    d. Papillomas of bile duct;
    e. Choledochal cyst;
3. **Type III: Chronic incomplete obstruction:**
        a) Strictures (Congenital, iatrogenic, sclerosing, post radiotherapy);
        b) Stenosed biliary-enteric anastomosis;
        c) Chronic pancreatitis;
        d) Cystic fibrosis;
        e) Stenosis of sphincter of Oddi.
4. **Type 4: Segmental obstruction:**
    a. Traumatic;
    b. Iatrogenic;

c. Sclerosing cholangitis;

d. Cholangiocarcinoma.

Once surgical obstructive jaundice is suspected, it is evaluated biochemically and radiologically. Biochemically, there is elevation of total bilurubin (usually greater than 10 mg/dL), with direct hyperbilurubinemia. Also, the serum alkaline phosphatase is increased as they are secreted by the ductal epithelial cells. There may also be an increase in other liver enzymes like aspartate transaminase, alanine transaminase and Gamma-glutamyl transferase.

CA 19-9 has been shown to elevate in cases of obstructive jaundice. It is mildly elevated in benign diseases, such as choledocholithiasis, while it is grossly elevated (to the level of 1000s.) in malignant obstructive jaundice. The normal range for CA 19-9 is 0-37 IU/L.

Radiological investigations as elucidated above are done in a systemic manner to arrive at the diagnosis, and rule out the differentials. Non-invasive imaging is preferred as it avoids the risk of ERCP associated complications. MRCP is a suitable alternative to ERCP to diagnose biliary duct pathology. ERCP, however, remains the gold standard for diagnosing bile duct pathology, but, its role in the diagnostic setting is being increasingly questioned in view of the high, normal ERCP reporting and also, higher risks of complication.

SURGICAL MANAGEMENT:

Clinical experience and data from current and older studies strongly suggest that, similar to the surgical management of duodenal ulcers, ***operative exploration of the CBD for stone disease is quickly becoming a thing of the past.***[32]

Wandling et al reported a decrease in the use of both open and laparoscopic common bile duct exploration (LCBDE) for patients with choledocholithiasis. While corresponding to this decrease in LCBDE with laparoscopic cholecystectomy (LC), the authors also noted a marked increase in the use of endoscopic retrogradecholangiopancreatography (ERCP) with LC to treat choledocholithiasis.

The authors also reported a shorter length of stay for patients treated with LCBDE + LC vs ERCP+LC, which was similar to results that had been previously reported.

While concern is expressed that CBDE may disappear from the surgical armamentarium, the ideal management for choledocholithiasis remains controversial. Both ERCP+LC and LCBDE+LC have been demonstrated to be minimally invasive and effective procedures.

In the study by Wandling et al, the use of LCBDE+ERCP+LC for patients with choledocholithiasis was at a very low level (1998, 3.9%;2013,1.5%), suggesting good duct clearance and therapeutic success obtained from either ERCP or LCBDE.

Previously, meta-analyses comparing single staged approaches (LCBDE+LC or intraoperative ERCP+LC) with the 2-stage approach (ERCP+LC) demonstrated that

both methods had similar clinical outcomes, although ERCP+LC was associated with a higher cost. Additional data from a prospective randomized trial, also suggested preferential outcomes for the1-stage approach (ie,LCBDE+LC) in terms of decreased hospital stay and better cost effectiveness. Despite these data,as noted by Wandling et al, the 2-stage technique, typically involving preoperative ERCP followed by LC, is more commonly used. There are several reasons for this.

One reason may be that LCBDE, both through the transcystic route and through choledochotomy, can be a technically demanding procedure that requires good laparoscopic skills, advanced equipment and rich clinical experience .In addition, techniques have evolved now, that virtually all common duct stones can successfully be extracted via ERCP with the use of lithotripsy, basket extraction, and other techniques. While ERCP+LC may be associated with ERCP-related morbidity, such as pancreatitis and possible reflux cholangitis caused by endoscopic sphincterotomy, the incidence of these complications is low.

Recently, laparoendoscopic rendezvous has been proposed as another means to treat choledocholithiasis. As a single-stage management, it reduces operation time, has lower technical difficulties, decreases post-ERCP pancreatitis, and can be used even in emergency cases. However, this approach usually requires the availability of both surgical and endoscopic teams in the operating room.

In the era of minimally invasive surgery and individualized medical care, the treatment selection for patients with choledocholithiasis should be decided based on:

a) the complexity of the disease,

b) cystic duct and;

c) CBD status (eg, the diameter and thickness),

d) anatomical variations,

e) history of gastrointestinal surgery,

f) and patient comorbidities.

g) In particular, the specific surgeon’s experience and the availability of the appropriate laparoscopic instruments can also play an important role.

In summary, the various treatment options for choledocholithiasis can be summarized in the following 2 diagrams:

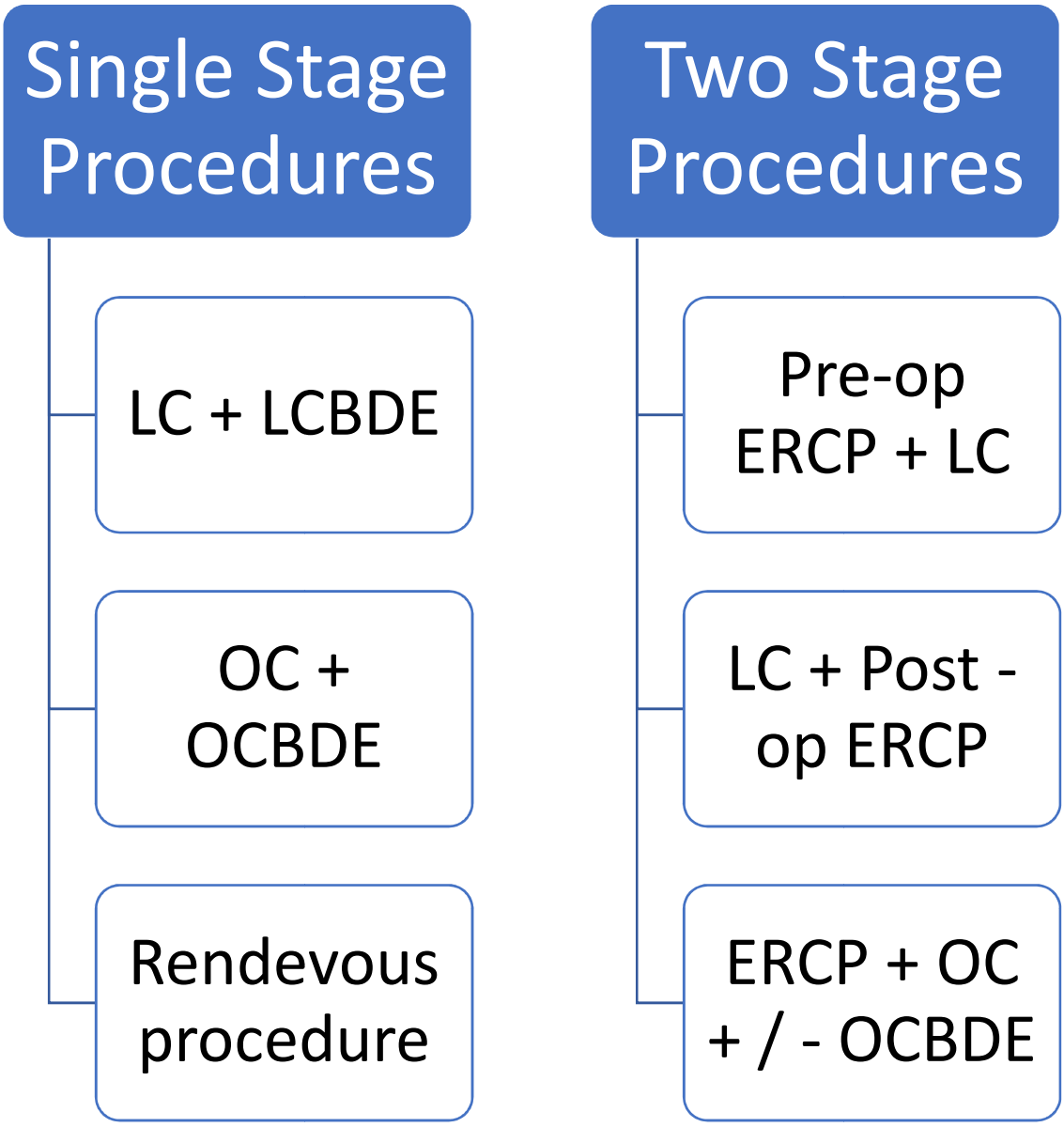

Fig. 7: Surgical Management of Choledocholithiasis

LC + LCBDE

- Advantages:
  - Single sitting
  - Lower cost
  - Minimaly invasive
- Disadvantage:
  - Technically demanding
  - Expertise and equipment, not availabe everywhere to reproduce similar results

Pre-op ERCP + LC

- Advantages:
  - ERCP techniques now suffficient to address most choledochal pathlogy
  - Technically, less demanding as compared LCBDE
  - More ubiquitous in availablity
- Disadvantages:
  - Two stage procedure;
  - Costlier vs LCBDE
  - Longer hospital stay vs LCBDE

OCBDE + OC

- Advantage
  - Single stage procedure
  - Only solution for ERCP failed, LCBDE failed Choledocholithiasis
  - Remains procedure of choice for difficult and complex CBD stones (select patient groups)
- Disadvantage
  - Slowly vanishing from armametorium of CBD stone management due to high morbidity
  - Higher cost
  - Not minimally invasive

Rendezvous procedure

- Advantages
  - Single stage
  - Minimally invasive
- Disadvantages
  - Both medical and surgical gastroenterologists needed at the same time in the theatre
  - Higher cost

LC + Post op ERCP

- Disadvantage
  - Post op ERCP failure
  - Two stage procedure

Fig. 8: Advantages and Disadvantages of various single and two stage procedures for management of CBD stones

MATERIALS AND METHODS

Table 1: Research Methodology

Study Centre	Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai
Duration of Study	March 2017 to September 2018
Study Design	Prospective Observational study
Sample Size	30 cases divided among 3 groups
Inclusion Criteria	All good-risk patients with classic signs, symptoms, and laboratory and abdominal imaging features of cholecystolithiasis and choledocholithiasis, not amenable to ERCP retrieval
Exclusion Criteria	Neonates, Paediatric (Age <12), Pregnant and patients with poor risk as per American Society of Anaesthesiologists grading (ASA 4)
IEC Clearance	Obtained (Attached Annexure 2)

Materials:

A detailed questionnaire (attached as Annexure 1) was filled in prospectively, noting all the clinical, radiological and biochemical parameters of each of the participants of the study.

30 patients from the departments of General Surgery, Minimal Access Surgery, Surgical and Medical Gastroenterology were selected, as per the selection criteria detailed in the study. Informed written consent (Annexure 3) was obtained in the patients own language, after reading out the patient information sheet (Annexure 3). Patients were sorted, based on patient characteristics, into 3 groups namely:

a. open cholecystectomy plus common bile duct exploration with primary closure or T-tube placement **(OC+OCBD+/-T);**
b. Open cholecystectomy plus common bile duct exploration with choledochoduodenostomy/ jejunostomy/ Hepatico-jejunostomy **(OC+OCBDE+CD/CJ/HJ);**
c. Laparoscopic cholecystectomy plus laparoscopic common bile duct exploration **(LC+LCBDE).**

The patients were studied till the end of the study period or till their death, whichever was earlier.

DEFINITIONS IN THIS STUDY:

A **"failed ERCP"** is defined in this study, as an endoscopic retrograde cholangio-pancreatico-graphic study and therapy in which the CBD has not been cleared off the radiologically identified common bile duct stones (both primary and secondary). It is also one which has been declared, by a unit chief of medical gastroenterology at our tertiary care institute, as one not amenable to removal by scientifically documented methods.

The causes of failed ERCP choledocholithiasis includes but not limited to the following:

1. **Technical factors:** Difficulty in cannulating the CBD/ampulla of vater; including impossibility in cannulating the Ampulla of vater (Post antrectomy/ GJ), Duodenal Diverticulum/ Peri-ampullary diverticulum, Biliary strictures, etc.
2. **Stone Factors:** Include size, site, number and durability;
3. **Patient Factors:** Non-cooperative, High ASA Grade;

The American Society for Gastrointestinal Endoscopy recommendations suggest a biliary cannulation rate of > 85% should be the goal for all endoscopists engaged in ERCP. The therapeutic options following failed biliary cannulation may include: (1) repeat endoscopic attempt; (2) percutaneous cholangiography; (3) endoscopic ultrasound (EUS)-guided bile duct puncture and drainage; and (4) surgical management.

Failed biliary cannulation was defined as the inability to gain deep and free access to the bile duct. Cholangiography alone without deep instrumentation of the bile duct was **not** recorded as being successful.

Schutz graded endoscopic retrograde cholangiopancreatography degree of difficulty for biliary procedures as follows:[14]

Table 2: Schutz Grading of ERCP difficulty

	Biliary procedures
Grade 1	Diagnostic cholangiogram
	Biliary cytology
	Standard sphincterotomy ± removal of stones < 10 mm
	Stricture dilatation/stent for extra-hepatic stricture
	or bile leak
Grade 2	Diagnostic cholangiogram with
	Billroth II anatomy
	Removal of CBD stones > 10 mm
	Stricture dilatation/stent for hilar tumors or benign intrahepatic strictures
Grade 3	Sphincter of Oddi manometry

	Biliary procedures
	Cholangioscopy
	Any therapy with Billroth II anatomy
	Removal of intrahepatic stones or any stones with lithotripsy

Recurrent CBD stones were defined as the detection of symptomatic bile duct stones no sooner than *6 months* after complete clearance of CBD stones, based on symptoms or signs of biliary complication.

Retained CBD stones was defined as the detection of symptomatic bile duct stones sooner than *6 months* after surgery for complete clearance of CBD stones, based on symptoms or signs of biliary complication.

Methodology:

The study was a prospective, observational study conducted in a tertiary care centre from March 2017 to September 2018, with the first 30 patients with ERCP failed choledocholithiasis taken into the study.

These patients (n = 30) subsequently underwent open or laparoscopic common bile duct exploration for complex biliary stone disease. Cases of CBD exploration managed successfully with ERCP were not included. Most of the patients were referrals from the institute of medical gastroenterology or other tertiary/secondary care centres in southern India. The decision to add a drainage (by means of a T-Tube or a choledocho-enterostomy) procedure to Open or Laparoscopic CBDE was based upon

a number of factors viz. a previous number of attempts by endoscopists, associated strictures, history of recurrent cholangitis episodes, available duct diameter (usually > 10 mm) and any prior upper abdominal surgeries performed. **The most important factor of these was the common bile duct diameter**, which was determined pre-operatively by means of an MRCP (Magnetic Resonance Cholangio pancreaticography), and assessed definitively intra-op.

The 30 patients included in the study were observed in three different treatment groups, viz. **A) OC+OCBD+/-T; B) OC+OCBDE+CD/CJ/HJ; C) LC+LCBDE.**

A combination of multiple factors was considered for making choice of open or laparoscopic management of the disease, and after extensive discussion with patient and family. Demographics, co-morbid conditions, presenting symptoms, blood investigations, imaging studies, operative data, postoperative variables including complications, and early follow-ups were examined. After patients had received a detailed explanation of the procedure and its potential risks and complications, informed consent was obtained for the surgery. OCBDE or LCBDE with/without T-tube/CDD/CDJ was performed mainly as an elective procedure.

The preoperative workup of patients mainly constituted but was not limited to routine hemograms, liver functions, and ultrasound abdomen. MRCP and ERCP findings were noted in all patients, including the reason quoted by the endoscopist for the “failure” of ERCP. MRCP findings were considered the most reliable[8] for the number of CBD stones, site of CBD stones, and diameter of common bile duct.

CA 19-9 was done in select patients, who had significant loss of weight and appetite in the history, and imaging suggested a malignant pathology, apart from stone disease.

The technical, operative details were recorded for the type of OCBDE and LCBDE performed. The principles followed for CBD exploration and choledochoduodenostomy/jejunostomy were similar in both conventional open surgery and laparoscopic surgery, with the aim of performing a wide, diamond-shaped anastomosis. All patients, in whom CDD/CDJ was performed, underwent side to side choledochoduodenostomy as originally described by Gliedman and Gold[9]. Side to side choledochoduodenostomy avoids circumferential mobilization and transection, without compromising the blood supply, allows larger anastomosis, and minimizes the chances of anastomotic leak[10].

OPEN CBDE +/- DRAINAGE PROCEDURES:

Choledochoduodenostomy, choledochojejunostomy, or sphincteroplasty are operative procedures for the treatment of difficult or recurrent biliary and pancreatic problems. The following is the description of Choledochoduodenostomy and Choledochojejunostomy techniques used in our study.

Choledochoduodenostomy:

A right subcostal incision is usually performed; The duodenum is widely mobilized by a generous Kocher maneuver, so that it can be approximated to the common bile duct without tension. A 2.0-2.5 cm longitudinal incision is made in the distal common bile duct, as close as possible to the area of stenosis or obstruction in patients with benign disease.

Fig. 9: Choledochotomy Incision

The duodenum and duct are joined by a posterior row of interrupted 3-0 silk sutures. The duodenum is opened longitudinally for a distance of 2.0-2.5 cm and a second row of interrupted 3-0 or 4-0 vicryl or PDS (Polydiaxonone) sutures is placed to approximate the ductal and duodenal mucosa (Fig. 10). A T-tube is used in patients with thin-walled ducts or difficult anastomoses. A final row of interrupted 3-0 silk sutures completes the anterior row of the anastomosis.

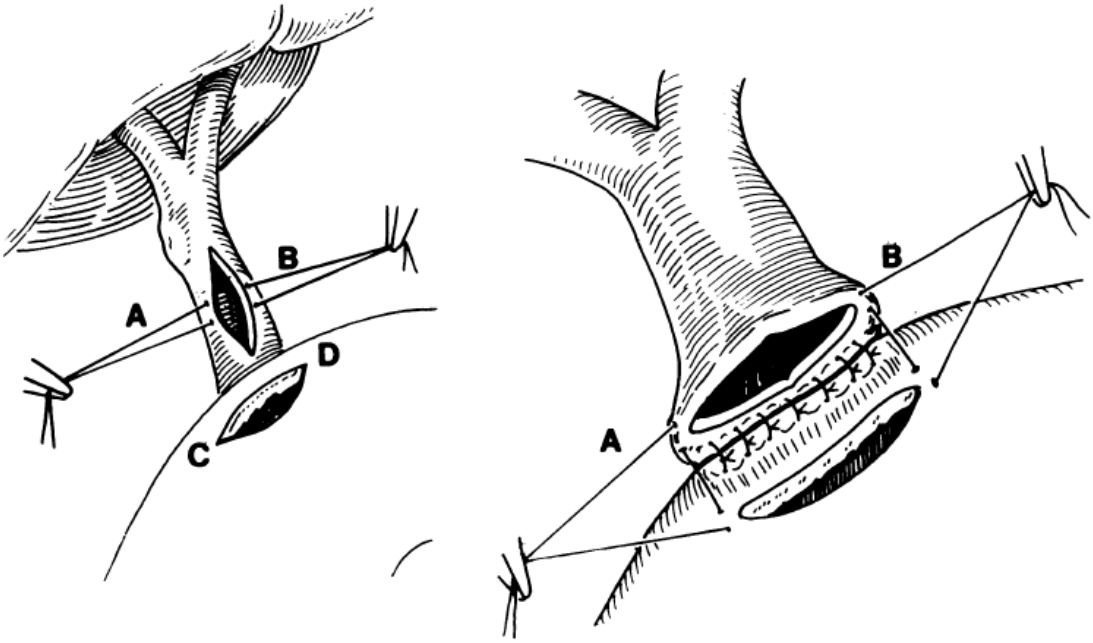

Fig. 10. Choledochoduodenostomy [9]

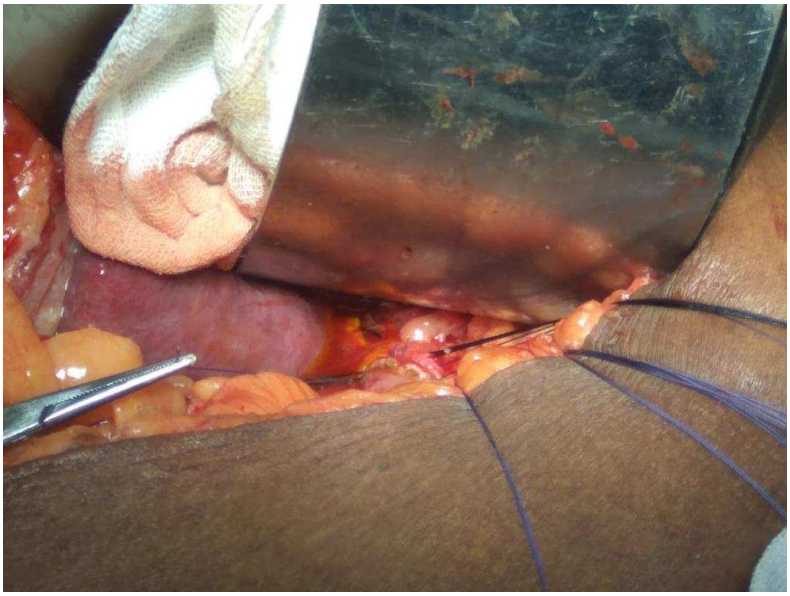

Fig. 11 A: Parachuting technique used in the diamond anastomosis for Choledocho-enterostomy

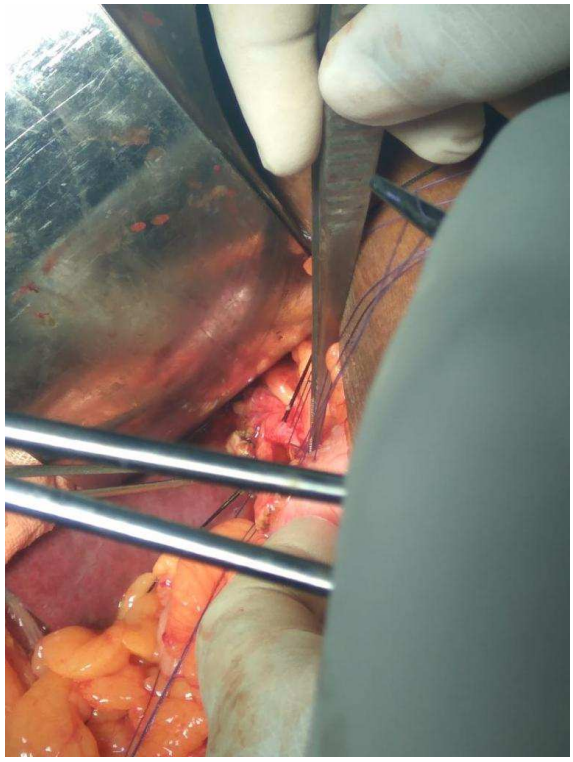

Fig. 11 B: Parachuting technique used in the diamond anastomosis for Choledocho-enterostomy

Choledochojejunostomy:

A right subcostal incision is again preferred, since it gives optimal exposure to the subhepatic area in most patients. The bile duct is exposed and a longitudinal, 2.0-2.5 cm opening is made in the distal duct for benign obstruction. A Roux-en-Y jejunal segment is prepared, the end of the jejunal limb is closed, and the jejunum approximated to the bile duct with a posterior row of interrupted 3-0 silk sutures. The jejunum is opened longitudinally for a distance of 2.0-2.5 cm and a second, inner row of interrupted 3-0 or 4-0 Vicryl or PDS are placed (Fig. 14). A T-tube may be used for selected patients with difficult anastomoses. A final row of interrupted 3-0 silk sutures on the anterior aspect completes the anastomosis.

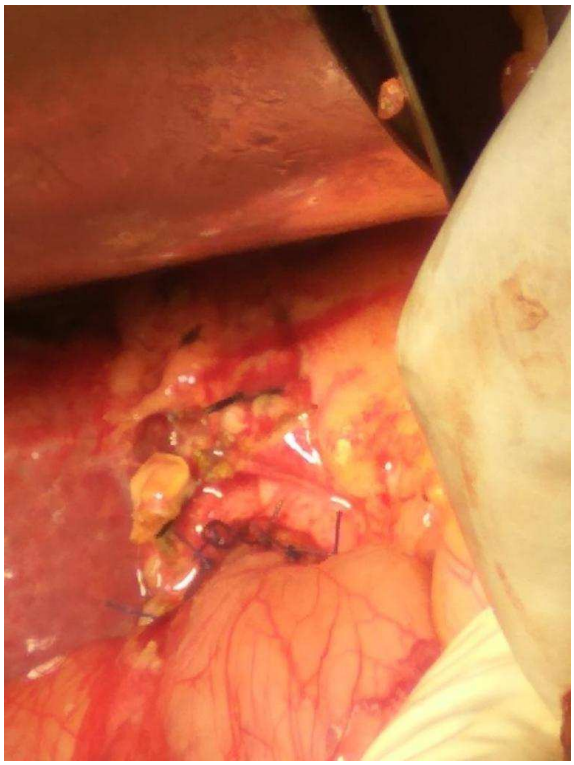

Fig. 12: Choledochoduodenostomy anastomosis complete

Fig. 13: Hepatolithiasis, Cholelithiasis with Choledocholithiasis in one of the cases studied; Total stone count was 49, with 9 stones identified in the CBD.

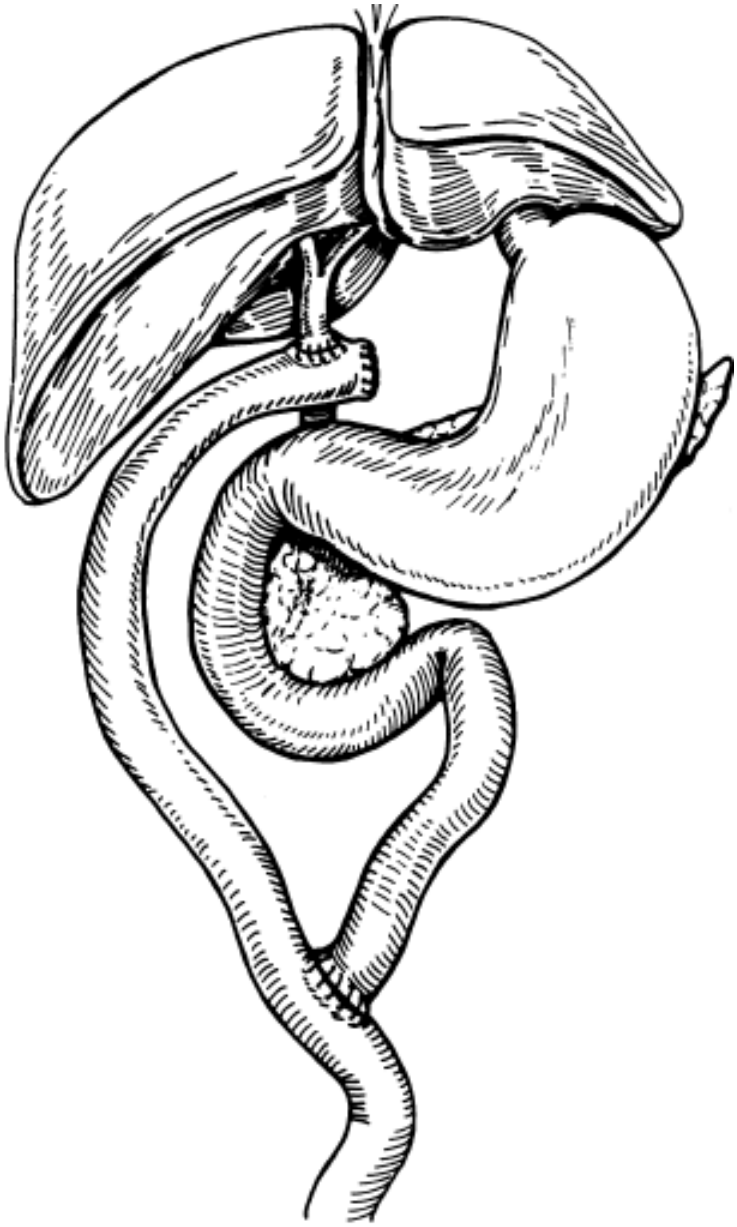

Fig. 14: Roux-en Y Choledochojejunostomy[9]

LAPAROSCOPIC CBDE +/- DRAINAGE PROCEDURES:

Patients underwent laparoscopic choledochoduodenostomy/enterostomy using a standard four-port technique with carbon dioxide pneumoperitoneum at 14 mm Hg pressure with a flow rate of 8 L/mt, using open Hasson's technique.

A 10 or 12-mm trocar was inserted in the umbilicus for the camera. Another 5 or 10-mm trocar was placed in the sub-xiphisternum as the primary working port. Two 5-mm trocars were put in the right upper quadrant 2 cm below the costal margin along the anterior axillary and mid-clavicular lines, respectively (Fig. 15).

A 30° angled video-laparoscope was used and placed through the umbilical port. Diagnostic laparoscopy was performed followed by the meticulous release of adhesions with blunt and sharp dissection, which was continued until the duodenum and the portal triad were defined.

After delineating Calot's anatomy, the cystic artery is clipped with an LT 300 titanium clip on either side and cut. Cystic duct is clipped, similarly with an LT 300/400 titanium clip, towards gall bladder (GB) and divided. GB should be left intact attached to the hepatic bed during the entire procedure as this helps in upward traction, exposing entire infrahepatic area.

To ensure a tension-free anastomosis, generous Kocher's maneuver was carried out in nearly all cases. The CBD is incised longitudinally with monopolar hook beginning at the point where it transverses the duodenum posteriorly and extending proximally about 2.5 cm.

Stone extraction is performed primarily by milking and further aided by saline irrigation using infant feeding tube. At this point, the previously placed stent, if any was removed. Both proximal and distal ducts are thoroughly rinsed with warm saline for clearing debris and infected fluid. Choledochoscopy was done through a 5-mm right subcostal port, using a choledochoscope or a rigid nephroscope, or at times by placing an extra port.

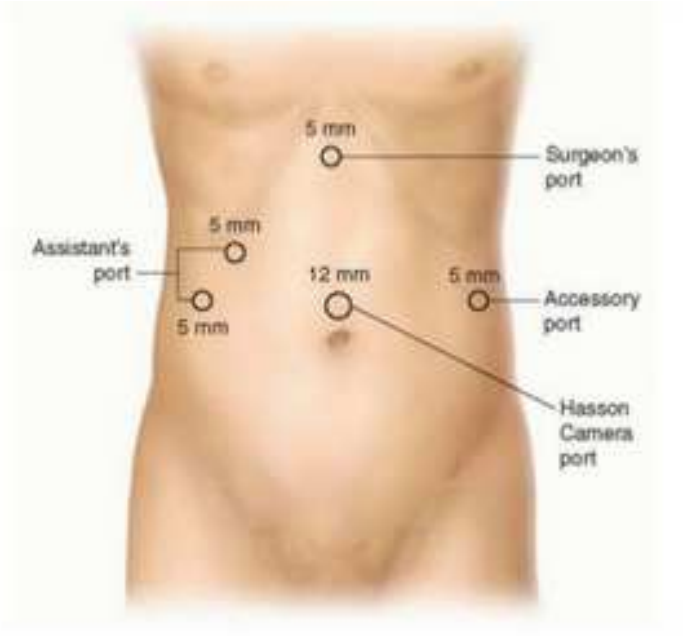

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Fig. 15: Port positions in LCBDE: **A** umbilical (10 mm camera) port. **B** Epigastric (10 mm) right-hand working port. **C** Right subcostal (5 mm) left hand working port. **D** Right mid axillary line (5 mm) port-gall bladder retraction

In situations of incomplete or unsuccessful stone clearance, the stones were localized, and various endoscopic instruments like baskets and balloons were used for

their removal, or converted to an open procedure. The duodenum is incised longitudinally along its superior border for a distance of approximately 1.5 cm.

A single-layer anastomosis is performed using 3-0 Vicryl/PDS interrupted sutures. After completion of the anastomosis, the gallbladder is removed from the liver bed and taken out in an endobag. A closed drain is placed in the lateral position to the anastomosis, headed toward Hepato-renal/ Morrison's space. Fascia and skin are approximated.

Patients were observed for at least a 12 hour period in an intensive care setting or a high-dependency unit. Orals were usually allowed as per the discretion of the operating surgeon, but preferentially at the earliest possible opportunity.

Patients were followed as outpatients after discharge with clinical examinations, liver function tests, ultrasound and/or to look for biochemical and radiological clearance of the Common Bile Duct, and to rule out any retained or recurrent stones. Post-op collections, cholangitic abscesses, and resolution of post-op pain were also followed up.

The outcomes measured in this study are as below:

A) The primary outcome measure will be stone clearance from the common bile duct – as indicated by decreasing bilirubin titres and radiological imaging (USG/MRCP as indicated).

B) Secondary end points include length of hospital stay, complications, morbidity and mortality, and patient acceptance (Likert Scale) and quality of life scores.

The collected data were analysed with IBM - SPSS statistics software 23.0 Version.

RESULTS AND ANALYSIS

- To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & standard deviation were used for continuous variables.
- To find the significant difference in the multivariate analysis the Kruskal Walli's test followed by the Mann-Whitney U test was used.
- To find the significance in categorical data Chi-Square test was used.
- In all the above statistical tools the probability value .05 is considered as significant level.
- The collected data were analysed with IBM - SPSS statistics software 23.0 Version.

Out of the total 30 patients who were selected in the study, all 30 had failed in endoscopic retrieval of stones as defined in the study as a FAILED ERCP.

I. DEMOGRAPHIC DATA ANALYSIS :

16 Males and 14 Females had been inducted into the study, among which 12 males and 11 females had been observed in the open group. The remaining 4 males and 3 females were in the laparoscopic wing. There was no gender prediction for the occurrence of CBD stones that would fail on ERCP guided retrieval.

The mean age of the patients in the study was 51.5 years. The mean age in the laparoscopic group was 37.7 years as compared to the mean age of 55.7 years in the open wing. The difference in the mean age observed in the two groups could be attributed to the lesser cardio-vascular and respiratory morbidity risk in younger patients in the laparoscopic group.

II. CLINICAL DATA ANALYSIS:

The clinical factors studied included the presenting and associated symptoms, the duration of symptoms, vital signs (Pulse Rate, Blood Pressure, Respiratory Rate and Temperature) and the clinical signs (especially the per-abdominal findings) at the time of presentation. The presence of pallor and icterus at the time of presentation was also noted.

The most common presenting symptom was abdominal pain, present in 90 % of the patients presenting with failed ERCP choledocholithiasis. The next most common symptoms were jaundice and vomiting. One of the cases presented with signs and symptoms of intestinal obstruction, which was ruled out after doing a contrast enhanced computed tomography (CECT) of the abdomen. Loss of weight and appetite were present only in 3 of the 30 patients studied (10%).

Symptom	Number of Patients presenting with the symptom	Percentage
Abdominal Pain	27	90 %
Jaundice	13	43.33 %
Vomiting	14	46.67 %
Fever	10	33.33 %
Dyspepsia	7	23.33 %

Table 3: Presenting Symptomatology in study population

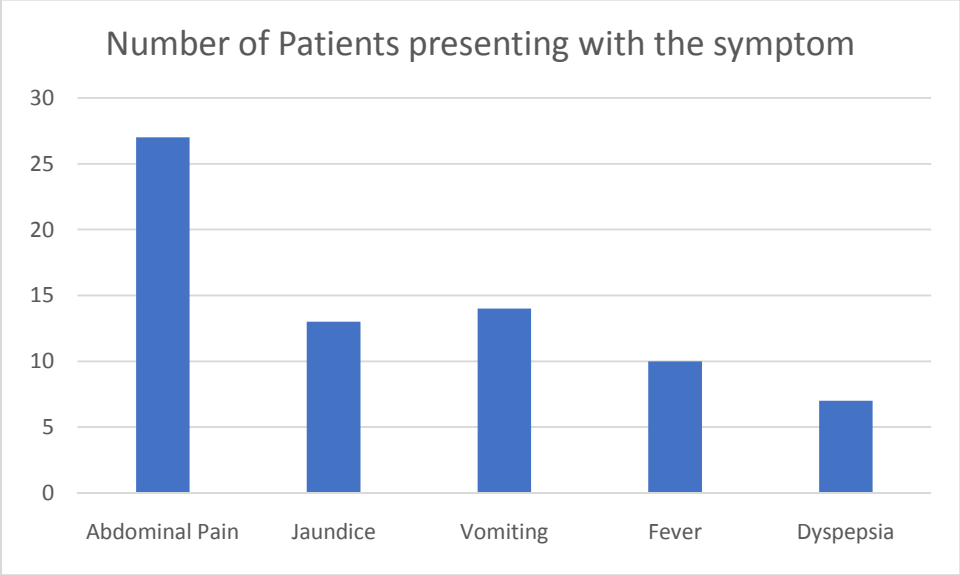


Fig. 16: Presenting Symptomatology in study population

The mean duration of symptoms was 5.97 (6) months (Standard Deviation 6.105; IQR -6).

The vital signs, both mean and median, were found to be in the normal range. Pallor was present in only 3 of the 30 patients studied (10 %). Similarly, icterus was noted only in 16 patients (53.33 %), implying that **only just over 50 % patients present with signs of jaundice at the time of admission.**

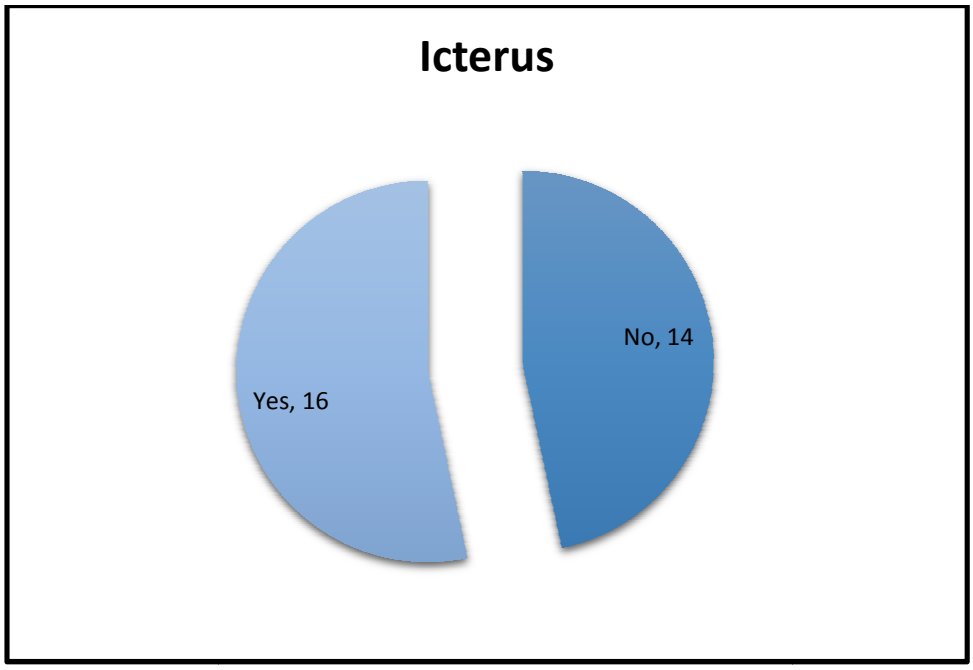


Fig. 17: Icterus was present in only 54 % of the patients with ERCP failed Choledocholithiasis

On analysing the per-abdominal examination findings of the study population, the following data was obtained:

Per Abdominal Findings	Number of patients (n = 30)	Percentage
Right Hypochondrial Tenderness	13	43.33 %
No abnormalities detected	11	36.67 %
Epigastric Tenderness	5	16.67 %
Hepato-spleenomegaly	2	6.67 %

Table 4: Clinical per-abdominal exam findings in study population

43 % of patients presented with right hypochondrial tenderness**, while 37% had no abnormal per-abdominal findings.** Thus, further investigation is warranted in patients presenting with abdominal pain with no abnormal clinical (particularly, per-abdominal exam) findings.

III. ANALYSIS OF BLOOD AND RADIOLOGICAL INVESTIGATIONS:

The mean haemoglobin was 12.23 g/dL, while the mean platelet count was 283.64 x 10^3/microL. The PT/INR was within normal range for all 30 patients. The **mean total bilirubin level was found to be 5.073 mg/dL** (Median = 2.450 mg/dL; SD = 5.38), **while mean SAP was 254.37 IU/L** (median was 211.00 IU/L). Total protein (mean) and total albumin (mean) were in the normal – 6.86 g/dL and 3.67 g/dL respectively. There was also no statistically significant difference in the presence of anemia, hyperbilurubinemia or hypoproteinemia between the three groups studied.

CA 19 – 9 was done in 8 of the 30 patients in the study. The investigation was done whenever there was a clinical or radiological suspicion of malignancy. None of the patients had a CA 19-9 value greater than 400 units/mL. **6 of the values (75 %) were greater than the normal range** of 0 – 37 units/mL, suggesting that a *mild* elevation of CA 19-9 values is consistent with benign obstructive jaundice patients.

Abdominal X-ray Erect (AP view) was found to be the least sensitive for picking up choledocholithiasis, with no AXR identifying any stones in the CBD. USG was the initial investigation of choice in patients with suspected surgical obstructive jaundice.

However, MRI (MRCP – Magnetic Resonance Cholangio-Pancreaticogrpahy) was considered the gold standard/ most reliable radiological investigation in this study. Hence, MRCP findings were used to define radiological characteristics of choledocholithiasis, prone to ERCP failure.

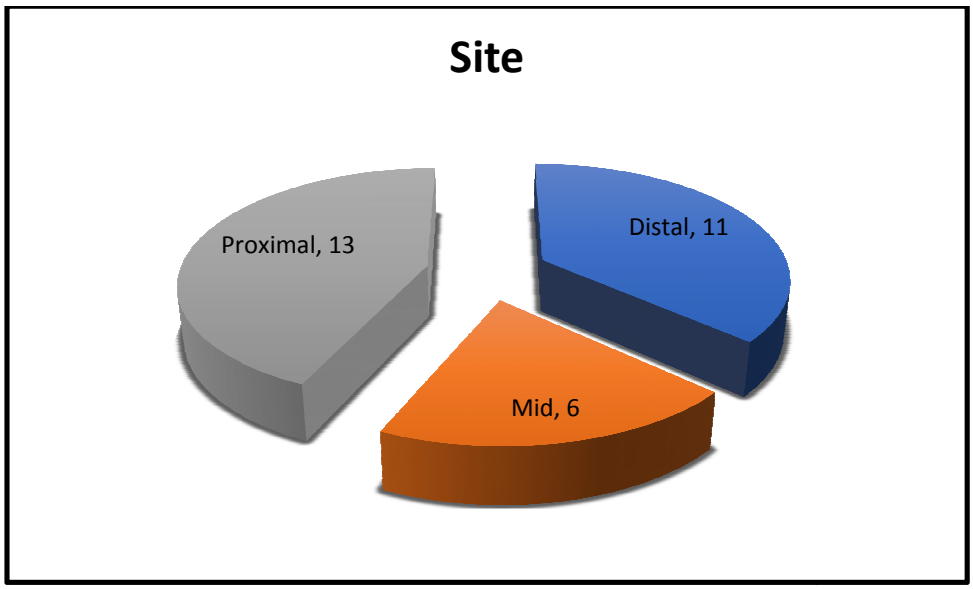


Fig. 18: Site of CBD stone and relative percentages

The following will be the characteristic of CBD stones prone for ERCP failure based on our study population (n = 30):

1. Number of stones > 3 (Mean 2.77; Median 2.50);
2. Site of the stone – Proximal 1/3rd (13 out of 30 cases);
3. Size of the stone > 14 mm (Mean 14.03 mm; Median 14);
4. CBD diameter > 14 mm (Mean 14.17 mm; Median 15).

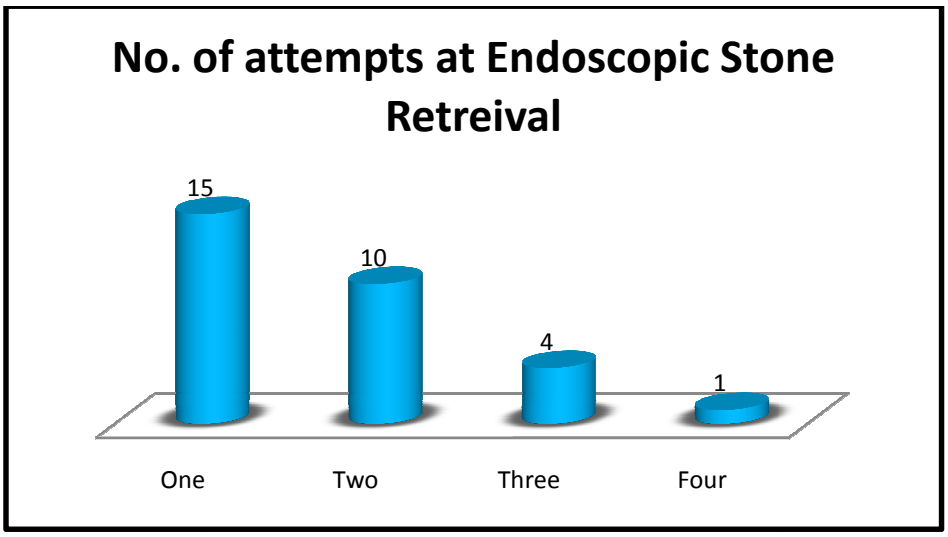


Fig. 19: Number of attempts at Endoscopic Stone Retreival

Also, the average number of attempts made to remove CBD stones, but all in vain was 2 (Mean - 1.70; Median 1.50). Hence, no more than 2 attempts should be made to extract CBD stones, endoscopically.

IV. ERCP FAILURE CAUSES:

The cause for ERCP failure was the single most important factor as defined by the chief medical gastroenterologist at our tertiary care institute and were classified into 3 headings, namely stone factors, technical factors and patient factors.

Factor	Specific Cause	Frequency
Stone Factors	Proximal CBD stone	6
	Mid CBD stone	1
	Large size of stone	6
	Multiple stones	4

Technical Factors	Impossible (Post GJ/CBD strictures)	5
	Failed Cannulation of the CBD	2
	Peri-ampullary Diverticulum (PAD)	2
	Choledochoduodenal Fistula	2
Patient Factors	Poor cardiac function/respiratory function	2

Table 5: Causes of ERCP failure (*n*=30)

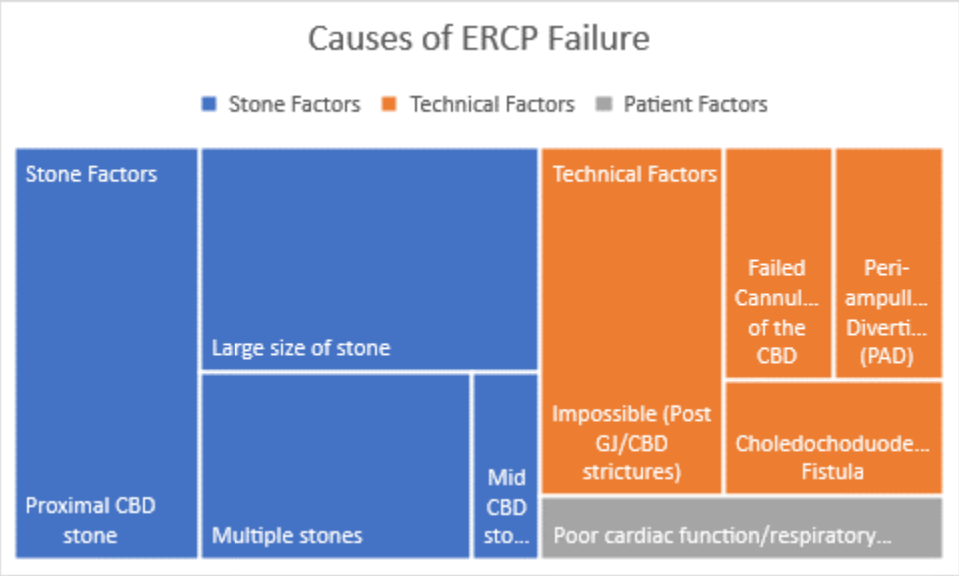


Fig. 20: Chart depicting the relative percentage of various causes of ERCP failure in our study population

The major reasons for failed ERCP stone clearance were as follows— stone factors - multiple large, proximal 1/3rd calculi (56.67 %), technical difficulties (36.67 %), and others (6.67 %).

V. SUB-GROUP ANALYSIS:

Three groups of patients were observed and followed up in our study –

a) the open CBD exploration with T-tube group, *n*=7;

b) the open CBD exploration with Choledochoduodenostomy/jejunostomy/ Hepaticojejunostomy group, *n*=16;

c) the laparoscopic CBD exploration group (with T tube/primary closure/CDD) group, *n* = 7;

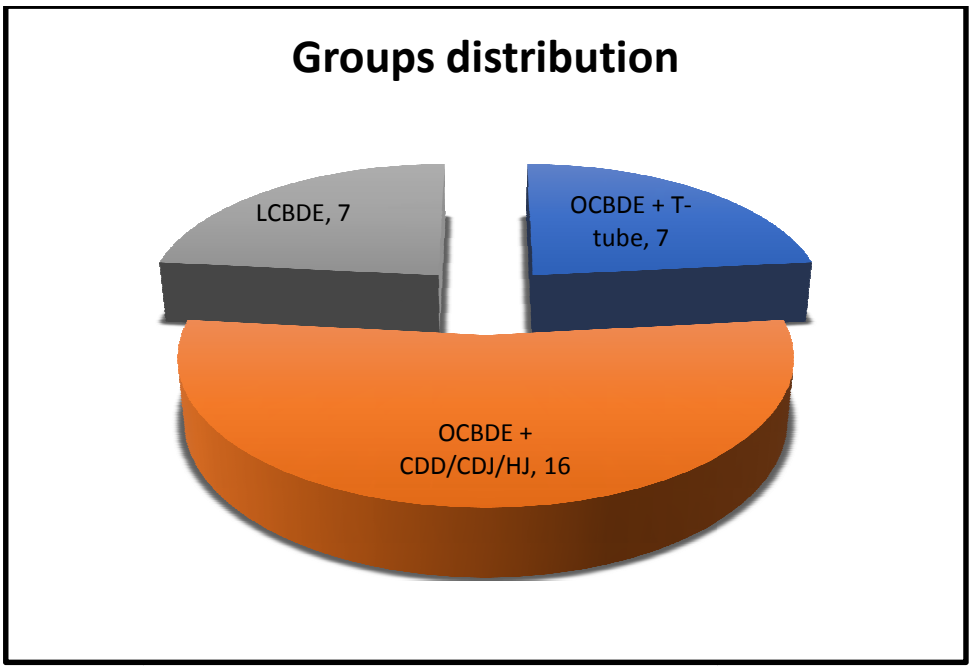


Fig. 21: Distribution of cases among the three study groups

It was found that none of the factors – age, sex, duration of symptoms, total bilirubin levels, Serum alkaline phosphatase levels, no. of attempts made for extraction of the CBD stone by ERCP and also the stone characteristics like number, largest size, site, CBD diameter, differed statistically among the 3 groups. Hence, the three groups were similar in these aspects.

The length of hospital stay among the three groups was similar and was, also, found not to be statistically significant. ***However, the QALY's (Quality Adjusted Life Years) lost differed statistically among the three groups (p < 0.001).*** It was lowest for the LCBDE group and highest for the Open CBDE + T-Tube group. Likert scales had highest values for the LCBDE group as compared to the Open CBDE groups, with the higher likert scores showing better patient satisfaction and perception of outcomes.

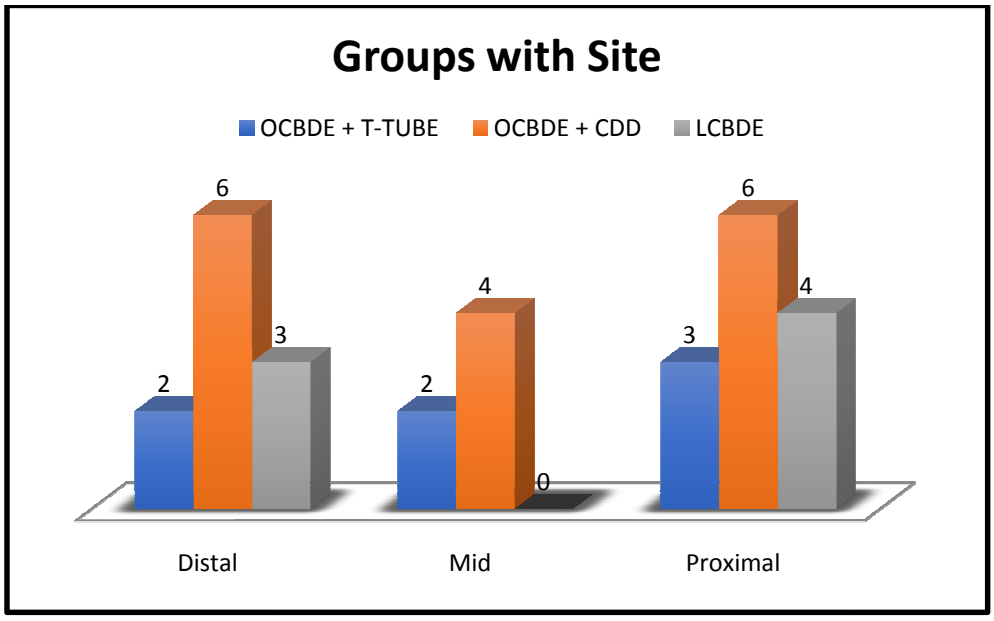


Fig. 22: Site of stones extracted in the 3 groups

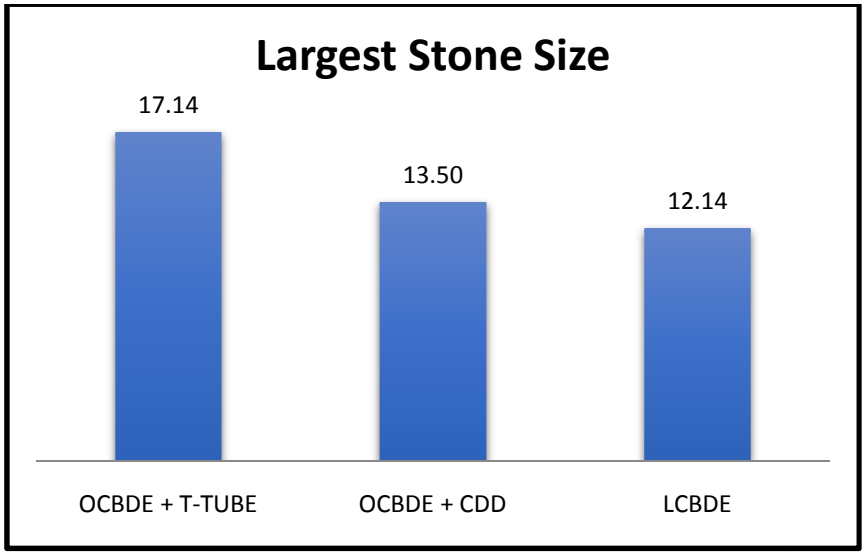


Fig. 23:Largest stone size in mm among the 3 groups (p-value = 0.234)

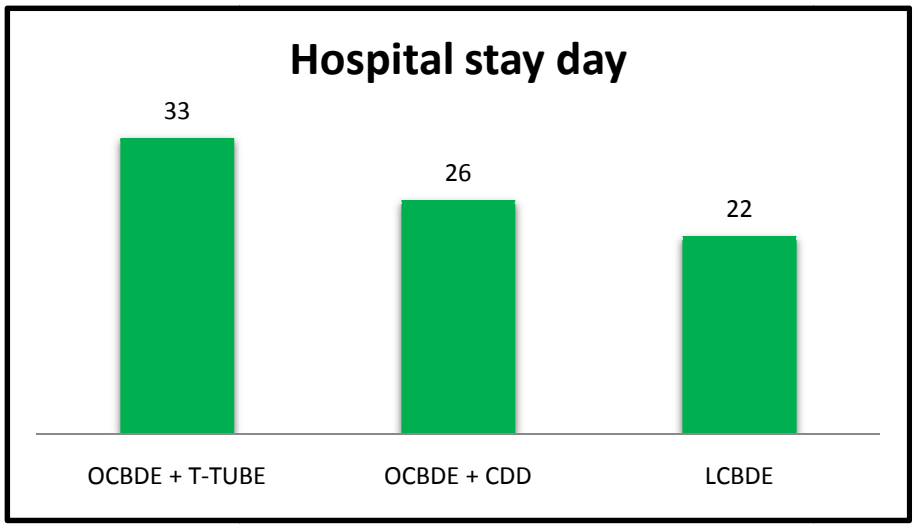


Fig. 24: The mean length of hospital stay among the 3 groups (p=.104) – Not Significant (*n* = 29)

The median length of hospital stay was 27 days (Mean = 26.83 days).

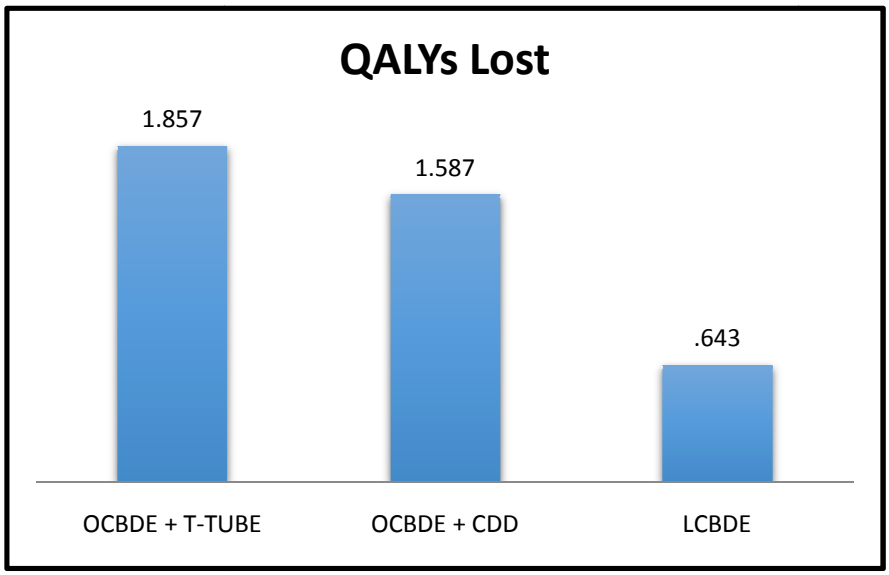


Fig. 25: Quality Adjusted Life Years Lost in the 3 groups (p=.001) – SIGNIFICANT STATISTICALLY (*n* = 29)

VI. OPERATIVE FACTORS:

Patients included in the study had an ASA grade of 3 or lesser. Almost all cases were assessed with an ASA grade of 1 or 2, except two patients who were graded 3 due to their cardio-vascular ailments, making them unfit for an ERCP. ASA grade 4 patients were excluded from the study as per the exclusion criteria.

Intra-operative findings correlated with the ERCP findings, except in two cases, where passed off CBD stones were diagnosed, and no stones were extracted.

Patients were followed up to the end of period of study. One mortality due to post-operative DVT was documented. Surgical Site Infections (SSI) was the most common post-operative complication. All cases achieved

complete biochemical and radiological clearance of CBD stones, except one case who had been closely followed up with T-tube Cholangiography, and post-op ERCP for subsequent stone removal. Morbidity due to the T-tube was highest in the OCBDE + T-tube group, because of the prolonged hospital stay and long follow-up periods.

The mean length of hospital stay for all the cases was 26.83 days (n = 29) and was highest for the OCBDE + T-tube group (33 days). The factors which influenced the length of hospital stay included the number of attempts at ERCP, the timing of decision for surgical intervention, and postoperative complications such as surgical site infections and peri-choledochal collections.

The average number of QALYs lost was 1.424 (n = 29) for all the three groups put together. It was least for the LCBDE group.

VII. BIOCHEMICAL ANALYSIS OF STONES:

Post-operative biochemical analysis of stones was done to assess the type of CBD stone most prone for ERCP failure.

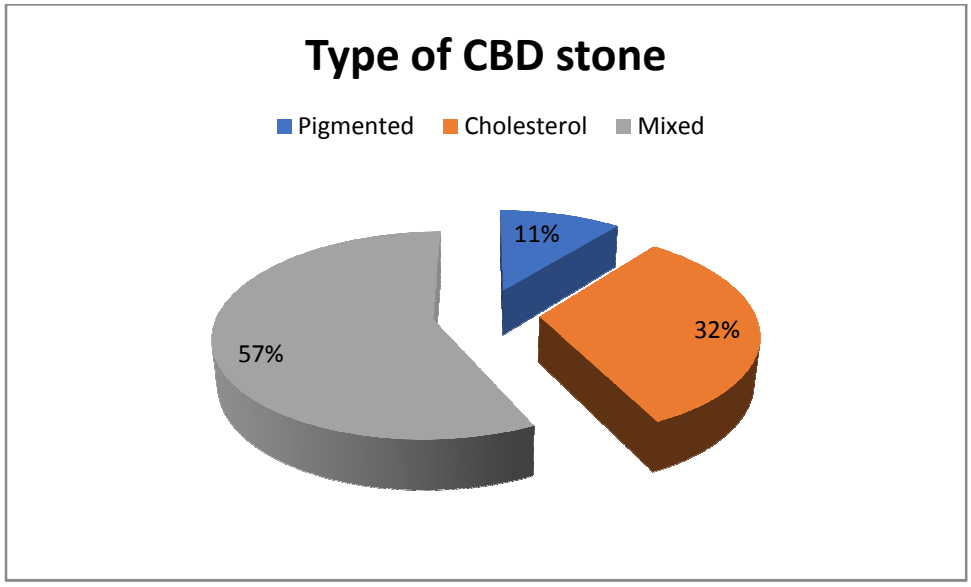


Fig. 26: Type of CBD stone and ERCP failure

DISCUSSION

Literature reports first choledochoduodenal anastomosis in 1888, by Riedel [16] for CBD calculi, while Franklin and Balli [17] are credited for replicating this procedure via minimally invasive (laparoscopic) approach in 1991. This procedure has evolved considerably since last 25 years. The enhanced role of successful endoscopic stone extraction has led to a change in patient's spectrum arriving at the surgeon's doorstep, as increasingly complex choledocholithiasis is forming the majority of referrals amongst those who underwent open or laparoscopic CBDE.

SINGLE VS TWO-STAGE PROCEDURE FOR MANAGEMENT OF CHOLEDOCHOLITHIASIS:

The ideal management of concomitant stones in the gallbladder and the common bile duct (CBD) remains controversial, as several options exist. Before the advent of laparoscopic and endoscopic methods, open cholecystectomy and CBD exploration were the standard treatment for patients with CBD stones. The introduction of laparoscopic cholecystectomy into clinical practice in 1989, [27, 28] ushered in a new era in the management of gallbladder and biliary disease with quicker recovery, less postoperative pain, and shorter duration of hospital stay.

Although not favoured in the "open era" for preoperative clearance of the bile duct, endoscopic retrograde cholangiopancreatography (ERCP) is often either used before or after laparoscopic cholecystectomy in patients with suspected (jaundiced patient, with elevated liver function tests, history of pancreatitis, or dilated CBD on radiographic imaging) or confirmed CBD stones on radiological investigations. This

trend may be related to the increased technical difficulty in performing laparoscopic common bile duct exploration (LCBDE). Nevertheless, while ERCP is highly effective in clearing stones in the biliary tree, this management option has also a number of disadvantages, including an up to 86% normal exam rate, when performed routinely. Short-term complications, while infrequent, may include pancreatitis, bleeding, perforation, and cholangitis. Further, division of the sphincter of Oddi leads to loss of this physiologic barrier, which in the long-term may lead to ampullary stenosis, duodenobiliary reflux, and recurrent stone formation.[2]

Refinements in technique and improvements in equipment have provided the tools necessary for surgeons with advanced laparoscopic training to effectively treat choledocholithiasis in a single-stage, laparoscopic procedure.

Thus, in essence the management of common bile duct stones can be divided into two:

- **Single stage procedures:**
    - Primary upfront Laparoscopic CBD exploration or open CBD exploration;
    - Hybrid procedure involving intra-operative ERCP and stone retrieval with laparoscopic cholecystectomy;

- **Two stage procedures:**
    - Pre-op ERCP – stone removal followed by Laparoscopic (or rarely, open) Cholecystectomy within 72 hrs of the successful ERCP;
    - Post-op ERCP – Stone retrieval after laparoscopic cholecystectomy, in the post-operative phase;

The advantage of a pre-operative ERCP and stone retrieval is that it provides us the opportunity to manage the choledocholithiasis, surgically too after a failed ERCP. The same is not possible in the post-operative ERCP group.

The non-availability of ubiquitous advanced laparoscopic expertise and equipment such as a choledochoscope or a lithotripter, encourage most surgeons to adopt a two stage technique of addressing the complex problem of choledocholithiasis, where most of them prefer a pre-operative ERCP +/- endoscopic sphincterotomy +/- stone retrieval, followed by laparoscopic cholecystectomy.[2]

Whenever the ERCP fails, a surgical management either by open or laparoscopic methods is offered in the form of an open or laparoscopic CBD exploration with or without a drainage procedure.

The most common indications for a choledochoenteric anastomosis or drainage procedure, available in world literature are multiple stones in the CBD, impacted CBD stones, intrahepatic stones (Hepatolithiasis), biliary stricture and recurrent calculi [18]. As patients with these situations often require multiple settings by

endoscopic means and are frequently associated with failed ERC clearance attempts, a choledochoduodenal anastomosis can be a valuable procedure for management of these "difficult stones".[18] So, a drainage procedure like CD, if added to Open CBD Exploration or Laparoscopic CBD Exploration in highly selected cases, can be a one-time solution, avoiding various complications and morbidities in the patient. The few studies exclusively reporting this approach have achieved excellent short- and long-term outcomes.

Currently, this method (Single Stage Laparoscopic CBD Exploration with or without Choledochoduodenostomy) is being accepted as the method of choice for the treatment of CBD strictures and complicated bile duct stones not amenable to successful treatment by ERC with excellent outcomes in 80–95% cases[19]. In this study, vital elements considered optimum and essential for the success of biliary drainage procedure like generous Kocher maneuver and selecting sufficiently dilated CBD diameter (> 1.2 cm) were not compromised during patient selection for such drainage procedures.

As evident from this study, we could achieve excellent drainage in both the laparoscopic group as well as the open group in the majority of patients without complication, with a resolution of jaundice in the long-term, as evidenced by radiological and biochemical clearance of CBD stones.

DEMOGRAPHIC AND CLINICAL PARAMETERS STUDIED:

Our patients were mostly elderly (51.5 years), with males outnumbering females by a very small percentage, this is similar to other reports published

earlier[14-16]. Younger patients were found to undergo the laparoscopic procedure more commonly than the open procedure.

The most common presenting symptom was abdominal pain, present in 90 % of the patients presenting with failed ERCP choledocholithiasis. The next most common symptoms were jaundice and vomiting.

Kaminski et al. in their study of 25 patients reported obstructive jaundice in 82% and pancreatitis in 17% cases[23], while Chander et al. [24] had (59.2%) patients with jaundice in a laparoscopic CBD exploration series.

40-50% of patients with choledocholithiasis may not demonstrate any historical, laboratory, or radiographic evidence of common duct stones preoperatively.[29] This was true in our study, where icterus was noted only in 16 patients (53.33 %), implying that only just over 50 % patients present with signs of jaundice at the time of admission. Also, no abnormalities were detected in the per abdominal examination of 36.67 % of the patients.

CAUSES OF FAILURE OF ERCP:

In a recent (2017) retrospective analysis of prospectively collected data done at an apex laparoscopic centre in southern India, out of total 30 patients who were included, 28 had a history of either failed ERC for stone extraction or those with multiple attempts. The rest of the two patients in the study were offered primary surgery in view of altered anatomy due to prior operative procedures (Roux en Y

Gastric Bypass (RYGB) and Gastrojejunostomy). In that study, the reasons for failed ERC and stone extraction (n = 28) were mainly multiple, large calculi [26.3 (± 0.3) mm] and CBD strictures. [18]

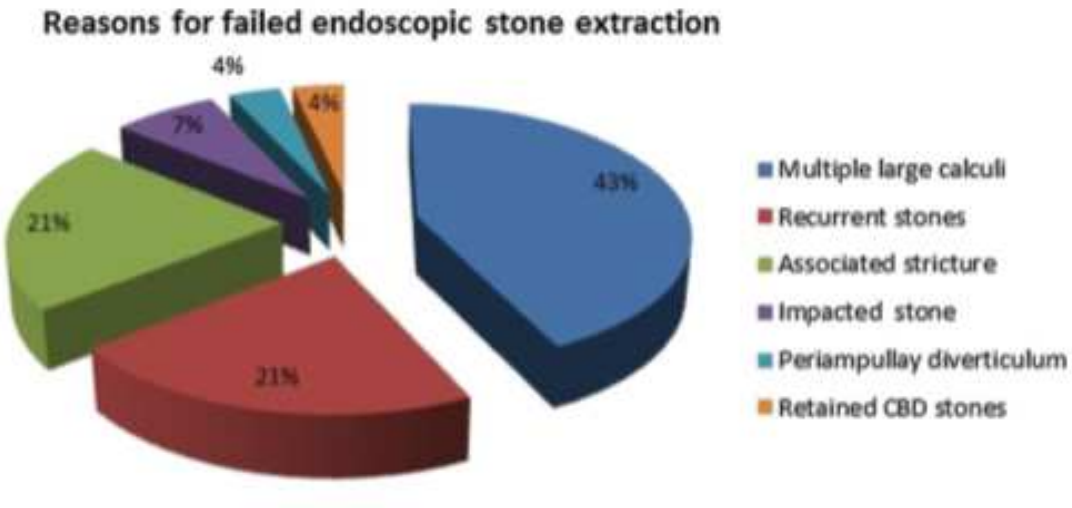


Fig. 27: Reasons for failed ERCP Choledocholithiasis according to the Senthilnathan P et al study (2017)

In another study conducted by Sanchez et al[30], which was a descriptive, comparative study of 25 patients having choledocholithiasis, 9 patients had failed with ERCP in the two-step wing offering upfront ERCP followed by laparoscopic cholecystectomy. In this study, patients with an indication of common bile duct exploration between February 2005 and October 2008 were included. They had studied 2 groups: Group A: patients with failed ERCP who underwent LCBDE plus LC. (Two-step wing) Group B: patients with common bile duct stones managed with the 1-step approach (LCBDE + LC) with no prior ERCP. (Single-step wing)

Failed ERCPs were due to the difficulty in cannulating the ampulla of Vater (4 patients) and difficulty in stone retrieval (5 patients), due to the presence of intrahepatic bile duct stones or huge common bile duct stones.

Causes	n = 9
Impossbility in Cannulating the Ampulla of Vater	
Antrectomy	1
Duodenal diverticulum	2
Not specified	1
2. Difficulty in Stone Retrieval	
Intrahepatic stones	2
Big and multiple stones	3

Table 6: Causes of ERCP Failure in Patients Admitted With Unresolved Choledocholithiasis as noted by Sanchez et al

These 9 patients had been operated on with the intention of performing LCBDE; however, the conversion rate to an open procedure was 33.3%, in view of the complex anatomy.

Intrahepatic bile duct stones and embedded stones in the ampulla of Vater were the cause of conversion to an open procedure. In a mean follow-up of 22 months, no residual lithiasis had been reported.

In our study, stone factors such as multiple, large stones were the most common cause of ERCP failure, accounting for almost 57% of the cases which failed with upfront ERCP. Also, technical factors such as periampullary diverticula, impossible CBD annulations (eg. Post Truncal vagotomy/Gastro-jejunostomy/Gastrectomy), and failed cannulation accounted for upto 37 % of the cases.

Thus, comparing all three studies, multiple, large stones seem to be the single most important factor determining ERCP failure in choledocholithiasis.

The definition of a difficult stone, as given by the three studies is tabulated below:

Study Name	Study Year	"Difficult" Stone size	Sample Size
Senthilnathan et al	2017	26 mm	30
Sanchez et al	2005	18 mm	9 (out of 25)
Our study	2018	14 mm	30

Table 7: Comparison of 3 studies

Inaccessibility to the ampulla/common bile duct via ERCP was noted in patients with previous history of gastric surgery, like truncal vagotomy and gastrojejunostomy. In our study, we had 5 patients with technical difficulty in accessing the CBD due to such rare circumstances. Choledochoduodenal fistula also happens to be a condition which cannot be dealt with by ERCP.

This peculiar situation in combination with choledocholithiasis can be effectively addressed by Choledochoduodenostomy, as reported by DuCoin et al.[25] in his experience of LCBDE with CDD in post-Roux-en-Y Gastric Bypass (RYGB) patients, who were diagnosed with CBD calculi.

Another approach, getting popular off late is laparoscopic trans-gastric ERC cannulation and stone clearance. The published literature suggests acceptable success rate, but the utility is especially limited in cases of associated lower CBD stricture, which poses a similar problem as in pre-op or post-op ERCP. [25]

Metabolic surgeries are known to cause rapid weight loss like a duodenal switch and RYGB, and are reportedly related to increased incidence of biliary calculi.[18] With growing popularity of metabolic surgeries, surgeons dealing with biliary disorders are likely to encounter this problem more frequently.

The laparoscopic biliary bypass (CDD/CDJ/HJ) has also been compared with an open counterpart for obstructive jaundice caused by benign lesions in a review by Jeyapalan et al. favors a minimally invasive approach in view of fewer complications (11.7 vs. 25%). We also a similar outcome in our study, which has indicated that the

Quality adjusted Life Years (QaLY) lost in laparoscopic drainage was must lesser than that in open drainage group ($p < 0.001$).

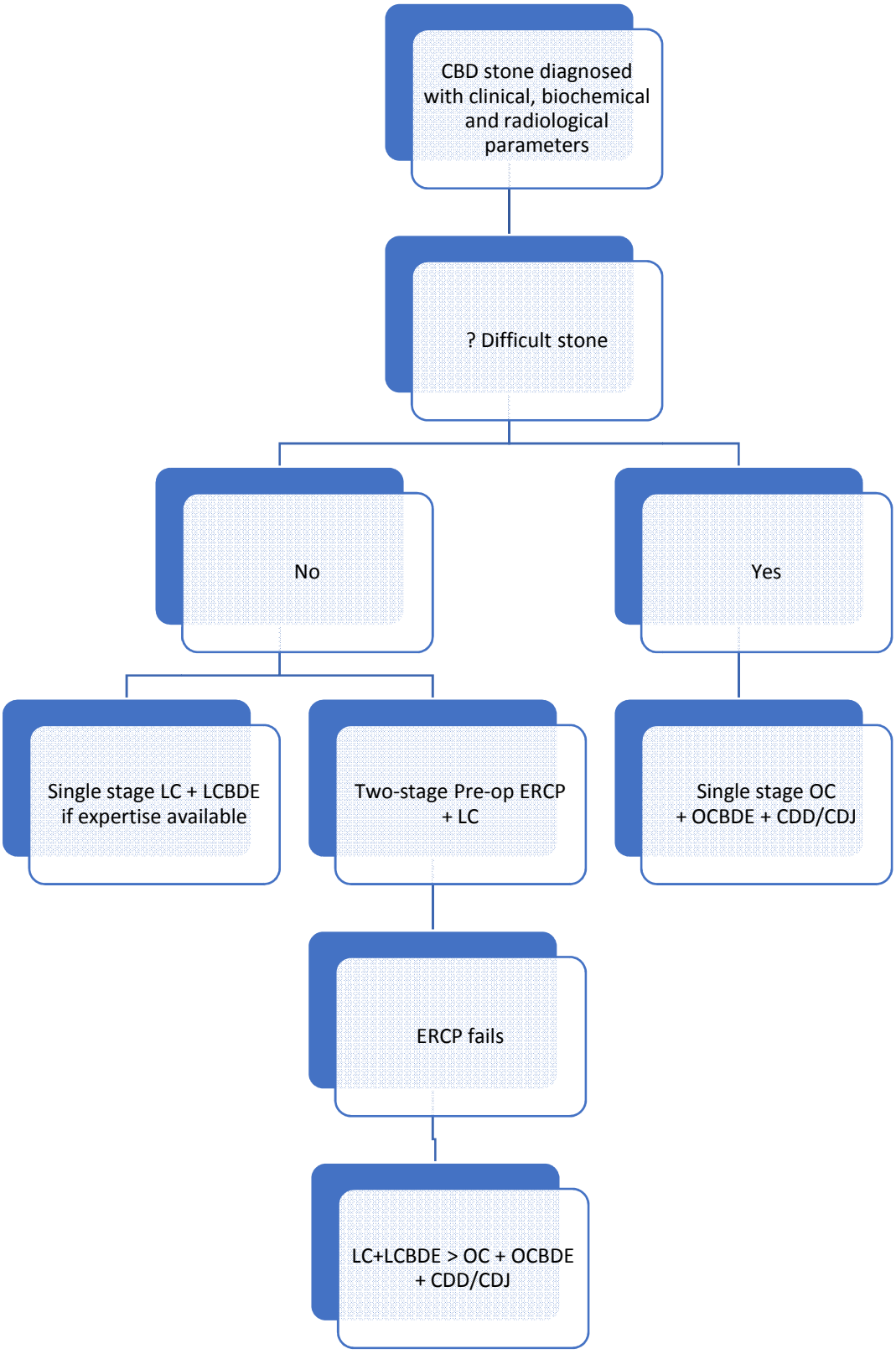
Some benefits of adding a bypass procedure to CBD exploration have been shown in studies, like decreased re-interventions, complications, and mortality[16].

Generally, in well-equipped centres of the world, ERCP followed by laparoscopic cholecystectomy is recommended as a safe, effective, and economical procedure. Several advanced laparoscopic centres advocate that laparoscopic cholecystectomy with common bile duct (CBD) exploration or a Rendezvous technique, where endoscopy and laparoscopy are performed simultaneously. They both have a similar efficacy profile with the added benefit of saving time.[18]

With the advent of all above-mentioned technologies, open surgical procedures, such as CBD exploration or biliary-enteric bypasses, are now usually considered obsolete. However, various studies point them out to be a definitive option in cases where ERCP fails to retrieve stones or where facilities of advanced laparoscopic surgery are not available.[26]

This study has attempted to analyze the outcome of adding a drainage procedure to CBD exploration by open and laparoscopic techniques to a highly selected group of patients having complicated bile duct stones, in terms of its effectiveness as the one-time procedure.

If one were to device an institution based **protocol for management of difficult CBD stones**, based on this study, it would look like the following flow chart (Fig. 28):



Definition of a difficult CBD stone according to the study:

A difficult CBD stone(s) is one which has characteristic features of choledocholithiasis, which is prone for ERCP failure based on our study population (n = 30). These characteristics are:

1. Number of stones > 3;
2. Site of the stone – Proximal 1/3rd;
3. Size of the stone > 14 mm;
4. CBD diameter > 14 mm;
5. And biochemically, a mixed stone.

LIMITATIONS OF STUDY:

The few limitations of the present study are

- relatively small patient population from a single center;
- the absence of comparator open arm, and;
- the non- availability of a regular surgical team with advanced laparoscopic skills and equipment, for offering a laparoscopic CBD exploration and drainage procedure, thus skewing more data on to the open CBD exploration wing;
- Follow-up of patients was for a short duration of time, thus, we could not determine recurrence of CBD stones in our patients.

In this study, we would like to suggest this approach in selective cases as a complimentary option to ERC stone removal and CBDE with primary repairs, but not as an alternative to them.

FUTURE SCOPE FOR STUDY:

A randomized control trial with blinding, would set to doubt any difference in offering a single stage with laparoscopic CBD exploration vs a two-stage ERCP followed by laparoscopic cholecystectomy, in the management of difficult choledocholithiasis.

Studies may also need to evaluate the possibility of offering an upfront laparoscopic cholecystectectomy with CBD exploration in a single siting, as the only factor hindering it is surgical expertise. This would bring down the morbidity associated with the two-stage procedure, and also save time, resources and loss of QaLYs for choledocholithiasis patients.

CONCLUSION

The characteristic features of choledocholithiasis, which is prone for ERCP failure based on our study population (n = 30) are

1. Number of stones > 3;
2. Site of the stone – Proximal 1/3rd;
3. Size of the stone > 14 mm;
4. CBD diameter > 14 mm;
5. And biochemically, a mixed stone.

There is no difference in the clinical outcomes, radiological, and biochemical clearance of CBD stones, length of hospital stay between Open CBD Exploration with T-tube or Chledochoenterostomy and Laparoscopic CBD Exploration, except for the Quality adjusted Life years lost, which is least in laparoscopic CBE exploration patients ($p < 0.001$).

The ideal management of choledocholithiasis remains controversial, but the treatment for choledocholithiasis must always be tailored to the needs of each patient.

LIST OF ABBREVIATIONS USED

(As they appear in the dissertation)

1. **CBD(S)** – Common Bile Duct (Stones);
2. **ERCP** - Endoscopic retrograde cholangiopancreatography; ERC – Endoscopic retrograde Cholangiography;
3. **QALYs** - Quality Adjusted Life Years;
4. **OC** - Open Cholecystectomy;
5. **OCBDE** – Open Common Bile Duct Exploration with primary closure or T-tube placement;
6. **OC+OCBD+/-T** – Open Common Bile Duct Exploration with primary closure or T-tube placement;
7. **OC+OCBDE+CDD/CDJ/HJ** - Open cholecystectomy plus common bile duct exploration with choledochoduodenostomy/ jejunostomy/ Hepatico-jejunostomy;
8. **LC -** Laparoscopic cholecystectomy;
9. **LCBDE -** Laparoscopic Common Bile Duct Exploration;
10. **MRCP –** Magnetic Resonance Cholangio-Pancreaticogrpahy;
11. **LT 300/400** – Liga Clip Titanium 300/400;
12. **ASA** – American Society of Anaesthesiologists;
13. **ERC –** Endoscopic Retrograde Cholangiography;
14. **EST** – Endoscopic Sphincterotomy;
15. **MDCT** – Multi Detector Computed Tomography;
16. **PTC** – Percutaneous Transhepatic Cholangiography;

17. **HIDA/PIPIDA/IODIDA –** Immuno-diacetic acid agents;
18. **SOD –** Sphincter of Oddi Dysfunction;
19. **PEP –** Post ERCP Pancreatitis;
20. **PDS –** Polydiaxonone;

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ANNEXURES

ANNEXURE 1

QUESTIONAIRE

PATIENT DETAILS:

Name: Age: Sex:

IP No.:

ON ADMISSION:

MAIN COMPLAINTS :

Abdominal Pain/ Vomiting/ Yellowish discoloration of eyes

ASSOCIATED COMPLAINTS:

Fever/ Pale stools/ Yellow coloured urine/ dyspepsia

CLINICAL EXAMINATION:

Pulse : BP :

RR : Temp :

Pallor : Icterus :

CVS : RS :

P/A : CNS:

INVESTIGATIONS :

CBC/RFT				
TC				
DC				
Hb %				
PCV				
RBC				
Platelets				
Glucose				
Urea				
Creatinine				
Na^+/K^+				

LFT				
Total Bili				
Dir. Bili				
SGOT				
SGPT				
Total Protein				
Sr. Albumin				

CA 19-9:

CXR :

Abdomen Xray :

USG Abdomen :

CECT Abdomen :

MRCP:

ERCP:

TREATMENT:

ASA Grade:

OPERATIVE MANAGEMENT:

1. OC + OCBDE + primary closure/
2. OC + OCBDE + T tube/
3. OC + OBCDE + CD/CJ/
4. LC + LCBDE

Indication:

Intra Op findings:

Post op Period:

Outcome measures:

1. Stone clearance from the common bile duct – as indicated by decreasing bilirubin titres and radiological imaging (USG/MRCP as indicated).
2. Total length of hospital stay;
3. Cost of index hospitalization;
4. Complications, morbidity and mortality, if any;
5. Patient acceptance – based on likert scale;
6. Quality of life scores based on QALY.

Post-op Biochemical and Pathological Analysis of CBD stone.

FOLLOW UP: Till end of study period/death.

ANNEXURE 2

Institutional Ethical Committee Clearance

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To

Dr.P.V.Sudharsan
I Year Post Graduate in M.S.General Surgery
Institute of General Surgery
Madras Medical College
Chennai 600 003

Dear Dr.P.V.Sudharsan,

The Institutional Ethics Committee has considered your request and approved your study titled **"A PROSPECTIVE STUDY ON THE CLINICAL OUTCOMES IN THE SURGICAL MANAGEMENT OF FAILED ERCP CHOLEDOCHOLITHIASIS – AN INSTITUTIONAL EXPERIENCE " - NO.20062017**

The following members of Ethics Committee were present in the meeting hold on **06.06.2017** conducted at Madras Medical College, Chennai 3

1. Prof.Dr.C.Rajendran, MD.,	:Chairperson
2. Prof.R.Narayana Babu,MD.,DCH., MMC,Ch-3	: Deputy Chairperson
3. Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3	: Member Secretary
4. Prof.N.Gopalakrishnan,MD,Director,Inst.of Nephrology,MMC,Ch	: Member
5.Prof.A.Pandiya Raj,Director, Inst. of Gen.Surgery,MMC	: Member
6.Prof.Rema Chandramohan,Prof.of Paediatrics,ICH,Chennai	: Member
7.Prof. Susila, Director, Inst. of Pharmacology,MMC,Ch-3	: Member
8.Prof.K.Ramadevi,MD., Director, Inst. of Bio-Chemistry,MMC,Ch-3	: Member
9.Thiru S.Govindasamy, BA.,BL,High Court,Chennai	: Lawyer
10.Tmt.Arnold Saulina, MA.,MSW.,	:Social Scientist
11.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3	: Lay Person

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

ANNEXURE 3

PATIENT INFORMATION SHEET AND CONSENT FORM

INFORMATION SHEET

TITLE: A Prospective study on the clinical outcomes in the surgical management of failed ERCP Choledocholithiasis – An institutional Experience

Name of Investigator: Dr. P.V. SUDHARSAN

Name of Participant:

Purpose of Research: To compare outcome parameters for good-risk patients with classic signs, symptoms, and laboratory and abdominal imaging features of cholecystolithiasis and choledocholithiasis, failed to be treated by ERCP randomized to open cholecystectomy plus common bile duct exploration with primary closure or T-tube placement (OC+OCBD+/-T) or open cholecystectomy plus common bile duct exploration with choledochoduodenostomy/ jejunostomy (OC+OCBDE+CD/CJ) or laparoscopic cholecystectomy plus laparoscopic common bile duct exploration (LC+LCBDE).

Study Design: Prospective randomized observational study

Study Procedures: Patient will be subjected to routine blood investigations, X-RAY, USG, CECT/MRCP and ERCP, CA 19-9, Operative Procedure as indicated.

Possible Risk: No additional risks to the patient

Possible benefits:

Devise a protocol for the management of Choledocholithiasis, not amenable to treatment by ERCP.

Confidentiality of the information obtained from you: The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Can you decide to stop participating in the study: Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time.

How will your decision to not participate in the study affect you : Your decision will not result in any loss of benefits to which you are otherwise entitled.

Signature of Investigator Signature of Participant

Date :

Place :

PATIENT CONSENT FORM

Study Detail : **A Prospective study on the clinical outcomes in the surgical management of failed ERCP Choledocholithiasis – An institutional Experience**

Study Centre : Rajiv Gandhi Government General Hospital, Chennai.

Patient's Name :

Patient's Age :

Patient may check (☑) these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ❑

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ❑

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the Ethics committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ❑

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ❑

I hereby consent to participate in this study ❑

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests and to undergo treatment ❑

Signature/thumb impression

Patient's Name and Address:

Signature of Investigator

Study Investigator's Name: Dr. P. V. Sudharsan

ANNEXURE 4A:

LIST OF TABLES

ANNEXURE 4B:

LIST OF FIGURES

CERTIFICATE - II

This is to certify that this dissertation work titled "**A PROSPECTIVE STUDY ON THE CLINICAL OUTCOMES IN THE SURGICAL MANAGEMENT OF FAILED ERCP CHOLEDOCHOLITHIASIS – AN INSTITUTIONAL EXPERIENCE"** of the candidate **DR. P. V. SUDHARSAN** with registration Number **221611013** for the award of **Master of Surgery Degree** in the branch of **General Surgery**. I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows **only 8 percentage of plagiarism in the dissertation.**

Place: Chennai
Date: 18-10-2018

GUIDE & SUPERVISOR
SIGN WITH SEAL.

OCBDE

Name	Age	Sex	IP No	Chief Complaints
Karthikeyan	40	M	840/14	Pain, Jaundice
Saratha	85	F	62928	Dyspepsia, Loss of weight
Parthasarathy	47	M	60313	Pain, Dyspepsia, Jaundice, Vomiting. Fever
Vijayalakshmi	48	F	63847	Abdominal Pain
Radha	24	F	67142	Pain, Vomiting, Jaundice
Mumtaj	56	F	63450	Pain,
Malliga	63	F	63549	Pain, Fever, Vomiting
Ponnammal	75	F	70811	Pain, Not passed stools
Velan	59	M	23500	Pain, Dyspepsia
Chandrammal	78	F	20411	Pain, Dyespepsia
Ramachandran	58	M	32614	Pain, Jaundice, Vomiting
Amutha	29	F	86860	Pain, Vomiting, LOA, LOW +
Sharath Babu	45	M	95199	Pain, vomiting, Fever,
Rajendran	35	M	34820	Pain, Vomiting, Jaundice
Subramani	70	M	37334	Pain, Jaundice
Gnanasekar	38	M	106760	Pain, Fever, Jaundice +
Thangaraj	65	M	98640	Pain, vomiting, Fever, Post chole 8 months back
Dhanalakshmi	66	F	33558	Pain, Vomiting, Fever, Jaundice
Malliga	59	F	74465	Pain, Vomiting, Fever, Jaundice +
Ravimannan	57	M	113333	Pain,Vomiting
Muthu	70	M	87283	Post Lap Chole, Stenting, Hiccoughs
Krishnan	65	M	10185	Pain
Vanitha Shyamala	50	F	88759	Pain, Vomiting, Fever
	1282 M; 11 F			
LCBDE	55.7			

Name	Age	Sex	IP No	Chief Complaints
Vaitheswaran	58	M	69110	Pain
Murugan	65	M	50647	Pain, Vomiting, Fever
Jagadeshwari	36	F	73387	Pain, Jaundice, Fever
Parimalam	55	F	118445	Jaundice, Pain, Fever, Vomiting
Gnanasundari	32	F	2400/17	Pain, Dyspepsia
Murugesan	51	M	55656/17	Jaundice, Dyspepsia, Fever,
Indumathy	25	M	19670	Pain, Jaundice,
	264 M, 3 F			
	37.7			
	51.5 16/14			

Duration of Symptoms in months	Associated Complaints	PR
12	No Fever, dyspepsia, vomiting	88
6	No h/o fever, abdominal pain, etc.	82
6	Nil	88
3	Vomiting +, h/o Jaundice +	71
12	No dyspepsia, fever	90
24	No jaundice, vomiting, fever	74
1	No Jaundice, Dyspepsia	62
1	No other symptoms	68
6	No other symptoms	54
1	No other symptoms	76
1	No Other symptoms	72
1	No dyspepsia, fever	88
5	No dyspepsia	85
6	No dyspepsia, fever	82
1	No other symptoms	80
1	LOA, LOW +	94
8	No other symptoms	82
12	No dyspepsia, LOA, LOW	110
6	No dyspepsia, LOA, LOW	86
6	No juandice/fever/LOA?LOW	86
12	No Jaundice	108
5	No other symptoms	82
5	No Jaundice	86

	Associated Complaints	PR
6	No fever, No vomiting, No dyspepsia, No Jaundice	88
1	Dyspepsia, Jaundice	94
2	No dyspepsia, Vomiting	88
1	None others	82
24	None others	76
2	None others	74
2	None others	74

BP (mmHg	RR	Temp	Pallor	Icterus	P/A findings	Hb (g/dL)	lets (10^3/
120/70	10	N	No	Yes	Rt. Hypochondrial tenderness	14.5	288
130/80	12	N	No	No	Rt. Hypochondrial tenderness	14.6	295
140/90	12	100	No	Yes	Rt. Hypochondrial tenderness	9.7	237
120/80	13	N	No	Yes	NAD	11.9	340
130/80	12	N	No	Yes	Epigastric Tenderness	12.3	312
140/90	18	N	No	No	NAD	12.3	521
140/70	15	99	No	Yes	Rt. Hypochondrial tenderness	11.6	280
120/70	15	N	Pallor	Yes	Rt. Hypochondrial tenderness	8.5	150
140/80	14	N	No	No	Rt. Hypochondrial tenderness	14.5	340
110/70	14	N	No	No	erness along previous surgica	13.8	320
110/80	11	N	No	Yes	NAD	11.8	298
110/70	12	N	Yes	Yes	megaly, Rt Hypochondrial te	7.1	167
130/80	13	N	No	No	NAD	14.3	234
130/80	11	N	No	Yes	NAD	14.2	270
110/80	14	N	No	Yes	atomegaly, Epigastric Tende	14.5	268
120/80	13	N	No	Yes	Epigastric Tenderness	11	342
110/70	12	N	No	Yes	NAD	12.8	179
100/70	24	N	Yes	Yes	Rt. Hypochondrial tenderness	5	56
130/90	12	N	No	No	Epigastric Tenderness	13.8	342
110/70	13	N	No	No	Rt. Hypochondrial tenderness	13.8	342
130/90	12	N	No	No	NAD	13.2	308
110/80	11	N	No	No	NAD	11.3	23
110/70	14	N	No	No	Rt. Hypochondrial tenderness	13.8	240
						280.3	6152
						12.19	

BP (mmHg	RR	Temp	Pallor	Icterus	P/A findings	Hb (g/dL)	lets (10^3/
120/80	13	N	No	No	NAD	14.4	268
120/80	14	N	No	No	Rt. Hypochondrial tenderness	10.8	356
130/70	12	N	No	N	Rt. Hypochondrial tenderness	12.1	491
120/80	14	N	No	Y	Heoatomegaly +	14	389
130/80	12	N	No	N	Rt. Hypochondrial tenderness	12.8	260
120/80	13	N	No	Y	NAD	10.2	240
130/80	12	N	No	Y	NAD	12.5	353
						86.8	2357
						12.4	
						12.23	283.64

C (10^3/Mi	PT/INR	ucose (mg/d	rea (mg/dL	atinine (mg+/K+ (MeqT	B (mg/dL	DB (mg/dL	GOT (IU/I
7.1	14/1.0	123	20	0.5	138/4.2	4.6	3.4	38
6.31	12/1.1	133	21	1.1	134/4.0	0.2	0.1	20
8.6	8.5/0.89	253	14	0.7	135/3.8	23.6	21.3	296
7.4	8.1/0.71	86	23	0.8	139/3.8	7	6.4	191
5	11/0.82	96	16	0.5	139/3.3	2.3	1.6	499
15.8	15/0.9	252	20	0.7	137/3.6	0.7	0.4	132
13.5	13/0.9	279	25	1.3	131/4.8	2.6	1.6	81
12.2	10/0.7	116	39	0.8	140/2.7	5.5	3.5	50
11.1	11/1.1	110	20	0.6	144/3.4	1.8	1.2	44
8.9	14.9/1.26	123	15	0.7	138/3.7	0.3	0.2	10
12.5	11/0.89	122	13	1	138/3.5	9.8	8.9	44
7.6	13/1.07	79	18	0.6	138/3.6	7.9	6.3	27
8	10/0.69	92	16	0.5	138/3.5	1.8	0.8	22
7.7	12/0.98	88	12	0.7	138/4.5	6.8	5.5	23
6.7	13/0.9	56	14	0.8	140/4.0	8.2	7.5	23
7.1	13.7/1.18	74	25	1	135/4.4	8.9	4.3	171
9.4	14.6/0.63	68	31	0.8	133/3.4	4.9	4.1	70
5.4	16.7/1.29	445	25	0.8	133/3.2	8.6	4.2	22
10.9	13.3/0.95	73	28	1.4	134/4.3	1	0.7	32
9.8	12.3/0.88	88	13	0.6	140/4.3	1.9	1.1	34
10.2	12.9/1.09	70	24	0.7	138/4.3	0.9	0.6	32
7.8	12.2/1.03	89	31	1	136/4.8	0.6	0.2	13
10.3	13.3/0.95	68	28	1.4	138/4.5	1	0.4	18

C (10^3/Mi	PT/INR	ucose (mg/d	rea (mg/dL	atinine (mg+/K+ (MeqT	B (mg/dL	DB (mg/dL	GOT (IU/I
9.6	13/1.1	169	23	0.6	138/4.1	0.8	0.2	15
9.8	0.94/1.09	130	39	1.5	134/4.3	1.5	1.2	262
10.6	13/1.24	106	14	0.7	150/4.3	0.4	0.2	30
16.4	12.2/1.03	116	59	2.8	133/3.2	12	8	87
8.1	11.9/0.98	138	22	0.7	144/3.8	0.9	0.2	38
13.5	16.2/1.03	240	16	0.9	138/4.1	11.7	5.5	20
6.5	13/1.2	84	19	0.9	136/4.0	14	7	13

GPT (IU/I	SAP (IU/L)	l Protein (g	Albumin (g	CA 19-9	ıy (AXR/C	SG Abdom	CECT Abdomen
28	144	8.2	3.6	NA	NAD	: with chole	Multiple CBD Calculi
10	38	5.3	3.1	NA	NAD	: with chole	Not done
257	699	5.4	5.9	138.5	NAD	ith distal ch	Not done
215	400	7.1	4.1	NA	NAD	: with chole	HBR + Distal CBD Cho
554	362	7.6	4.6	NA	NAD	IHBR Dila	5 mm Distal CBD stone
87	215	7	3.6	NA	NAD	atation, CB	NAD
176	469	7.1	3.5	124.9	NAD	Cholelithiasi	Choledocholithiasis
40	189	5.4	2.4	NA	stinal obstr	Obstructio	s with Choledocholithias
32	244	7.1	3.3	NA	NAD	IBR, ? CBD	lithiasis + Choledocholit
17	90	7.1	3.7	NA	NAD	R, ? Choled	Choledocholithiasis
67	299	7.2	3.6	NA	NAD	locholithias	Large distal CBD stone
26	91	7.1	4.1	19.6	NAD	holelithiasis	docholithiasis + Cholelit
20	190	7.4	4.3	NA	NAD	locholithias	Choledocholithiasis
22	207	6.8	4.3	NA	NAD	tation, ? Ch	ocholithiasis with Cholel
20	324	6.8	4.2	70	NAD	BR +. Chol	ocholithiasis, Distal CBI
184	347	6.6	3.2	110	NAD	atation, CB	ng, Pneumatosis+, CBD
51	483	7.2	2.4	NA	NAD	on, post ch	Proximal CBD stone
40	103	6.9	2.9	NA	NAD	pleenomeg	Not done
27	193	7.9	3.8	4.7	NAD	with chole	Proximal CHD lesion
20	78	6.9	3.8	NA	NAD	d, distal CB	ed Duaodenal bulb, CBI
28	70	6.3	3.5	NA	NAD	NAD	edocholithiasis, Cholelitl
18	70	6.6	3	NA	NAD	IHBR, CBI	ntracted GB. CBD calc
22	462	6.9	3.8	NA	NAD	Cholelithiasi	Not done
		157.9	84.7				

GPT (IU/I	SAP (IU/L)	l Protein (g	Albumin (g	CA 19-9	ıy (AXR/C	SG Abdom	CECT Abdomen
70	43	7	4.1	NA	NAD	cholithiasis	Not Done
83	255	7.3	3	NA	NAD	ted with Di	9 mm Distal CBD stone
27	144	6.7	4.1	NA	NAD	sis +Chole	depato+Choledocholithias
160	394	6.4	3.2	353	NAD	GB, Proxim	Multiple GB calculi
242	144	7.7	4.2	NA	NAD	lated, Chol	Not Done
42	568		3.6	5.3	NAD	hiasis, Cho	Not done
18	316	5.9	3.2	NA	NAD	with Chole	Not Done
		41	25.4				
		6.86	3.67				

MRCP	ERCP	No. of attempts
3 calculi/13 mm	Failed; Proximal CBD	4
1 calculus/12 mm	Failed: CA stomach associated	1
4 calculi/10 mm	Failed; patient unstable	1
5 calculi, 18 mm,	Failed: Multiple CBD + Proximal	2
2 calculi/ 12 mm	Failed; ? Distal CBD stricture	1
culi/ 12 mm + Type 1 Mirrizi - neck of GB	ed stone + Periampullary diverticulur	2
5 calculi, 12 mm,	Failed, Distal CBD stricture	1
ıted IHBR, Distal CBD stone +, Cholelithias	Failed; High Pulmonary Risk	2
1 calculus/12 mm	Failed; Mid-CBD stricture	1
4 calculi/15 mm	Peri-ampullary Diverticulum, Ampull	2
ithiasis/ Choledocholithiasis -18 mm from a	rge Periampullary diverticulum, Large	1
2 calculi/ 9 mm	Failed, Mid CBD stone	2
5 calculi/15 mm	Failed, Multiple calculi, Proximal	2
4 calculi/ 16 mm	Failed, Multiple stone, Biliary sludge	3
2 calculi/ 17 mm	Failed, Large Multiple stone	1
Sludge in CBD +, Mid CBD cal +	Failed, Stenting done, Sludge ++	2
3 calculi, 15 mm	oduodenal fistula, Proximal CBD sto	3
4 calculi, 10	Failed, Proximal stone	2
3 calculi, 15 mm	Failed, Proximal, Multiple stones	1
3 calculi, 11 mm	eformed pylorus, duodenal buld, D2 n	1
4 calculi, 15 mm	Failed, Multiple/Recurrent stones	2
1 stone, 16 mm	ngle/Large/Distal, Choledochoduoden	3
IHBR Dilataion, 18	Failed, Large stone	1

MRCP	ERCP	No. of attempts
2 calculi/ 11 mm	Hilar calculi - Failed	1
1 calculus/ 13mm	Failed; Post TV/GJ	1
Multiple Intra-hepatic +Distal CBD calculi	Cannulation Difficult, Only 1 stone r	2
3 calculi/14	Failed, Proximal large stone	1
Distal CBD calculus 1/16	Failed, Large stone	1
Proximal CBD stone; 12	Failed; Proximal stone + Cholangitis	3
Distal CBD calculus/ 18	Failed; Large stone	1

No. of stones	Site (Proximal/Mid/Distal)	Largest CBD Diameter (mm)
3	Proximal	13
1	Proximal	12
4	Distal	10
5	Proximal + Mid + Distal	18
2	Distal	12
2	Proximal + Distal	18
5	Proximal + Mid	12
1	Distal	18
1	Mid	12
4	Mid, Distal RETAINED STONE	15
1	Distal	18
2	Mid	9
5	Mid + Distal	15
4	Mid, Distal	16
2	Distal	17
3	Mid	15
3	Proximal and distal	15
4	Proximal	10
3	Proximal	15
3	Proximal + Distal	11
4	Distal, Mid	15
1	Distal	16
2	Distal	18

No. of stones	Site (Proximal/Mid/Distal)	Largest CBD Diameter (mm)
2	Proximal	10
1	Distal	13
> 8	Hepatolithiasis + Proximal + Dista	12
3	Proximal	14
1	Distla	16
1	Proximal	12
1	Distal	18

ze in mm (MRCP > ERCP	ASA Grade	OC/LC
18	2	**C+OCBDE + T-Tub**
20	2	E + HJ (OC done 30 y
6	3	OC+OCBDE + HJ
11	2	**C+OCBDE + T-Tub**
5	1	**C+OCBDE+T-Tube**
15	2	C + OCBDE + CDD
10	2	C + OCBDE + CDD
11	3	OC+OCBDE+CDD
16	2	C + OCBDE + CDJ
23	2	**OCBDE+ T-Tube**
25	2	**C + OCBDE + T-Tu**
14	2	**C +OCBDE + T-Tub**
14	2	OC+OCBDE+CDJ
15	2	C + OCBDE + CDD
19	2	C+ OCBDE + CDJ
8	1	C + OCBDE + CDD
17	2	OCBDE+CDD
16	2	OC+OCBDE+CDD
24	2	**C+OCBDE+T-tube**
6	3	+OCBDE (Transcys
16	2	OCBDE + CDD
15	2	C+OCBDE+RNY CD
12	2	OC+OCBDE+CDD

ze in mm (MRCP > ERCP	ASA Grade	OC/LC
11	2	DE + Primary Closure
9	2	**LC+LCBDE+T-Tube**
13	2	LC+LCBDE+CDD
12	2	DE + Primary Closure
15	1	**LC+LCBDE+T-Tube**
12	2	DE + Primary Closure
13	2	LC+LCBDE+CDD

Intra-op findings (No. of stones/complete clearance)	Complication if any	ical Stone C
Proximal + Distal CBD stone	ıed stones; pericholedochal coll	No
CA stomach +1 stone	None	Y
No CBD calculi intra-op	SSI	Y
Multiple CBD stone, CBD not as dilated	None	Y
le distal CBD stone with anteriorly placed hepatic artery; No stri	SSI	Y
ıltiple CBD stone (20 mm), Mirizzi + Cholecysto-choledochal fist	None	Y
Multiple CBD calculi + Distal CBD narrowing	Post ERCP pancreatitis	Y
Single Distal CBD stone.	Nil	Y
Single stone + Stricture	SSI	Y
Multiple stones +, CBD dilated	Dehiscence	Y
Single Distal CBD stone	None	Y
CBD not dilated, Stones +	SSI	Y
Multiple stones	Death	Y
Multiple stones with sludge	Wound dehiscence	Y
2 stons, CBD dilated	SSI	Y
Cholecystitis changes, Friable CBD stones +	Dehiscence	Y
Dilated CBD with multiple Calculi, Peri-Choledochal adhesions	None	Y
Multiple stones	None	Y
ultiple stones + soft tissue debris ? Tumor thromus ? Hydatid debris		Y
Multiple stones	SSI	Y
Multiple stones, Piecemeal removal of stones	None	Y
Large stone in distal CBD	SSI	Y
? Passed off stone	None	Y

Intra-op findings (No. of stones/complete clearance)	Complication if any	ical Stone C
2 stones	None	Y
10 mm stone +	None	Y
Multiple stons in CBD and hepatic ducts	None	Y
Stones +	None	Y
Single Large stone	None	Y
No stone, Sludge +	None	Y
Single distal CBD stone	None	Y

ical Stone	tal Stay (in	Morbidity	Likert (10 - Best,	ALYs Lo	ate of Surgery	Stone Analysis
No	44	done, ERCI	2	3.4	11-Jan	Mixed
Y	18	None	5	1.8	14-Jun	Mixed
Y	14	None	7	1.2	11-Jun	Mixed
Y	22	-Tube insit	2	1.2	13-Jun	Mixed
Y	19	-Tube in sit	4	2	23-Jun	Pigmented
Y	18	None	5	1.8	23-Jun	Cholesterol
Y	22	None	5	1.2	29-Jun	Cholesterol
Y	33	None	5	1	28-Jul-17	Mixed
Y	28	None	6	1.2	Dec-16	MIxed
Y	43	Γ-tube insitu	3	1.8	Mar-17	Mixed
Y	28	Γ-tube insitu	4	1	18-Apr-17	Mixed
Y	48	Γ-tube insitu	6	1.8	7-Sep	Cholesterol
Y	Death	Death	Death	Death	25-Sep	Mixed
Y	31	None	5	1.2	17-Apr-17	Cholesterol
Y	37	None	5	1.8	9-May-17	Mixed
Y	20	None	6	1	27-Sep	Cholesterol
Y	58	None	2	2.4	1-Oct	Mixed
Y	14	None	6	1.2	Apr-17	Cholesterol
Y	28	None	4	1.8	Sep-17	Mixed
Y	30	None	5	1.2	Nov-17	Mixed
Y	25	None	4	2.4	Sep-17	Mixed
Y	25	None	2	3.2	Mar-16	Pigmented
Y	20	None	7	1.2	Sep-17	

ical Stone	tal Stay (in	Morbidity	Likert (10 - Best,	ALYs Lost		
Y	12	None	8	0.6	14-Jul	Cholesterol
Y	26	Γ-tube insitu	5	1.2	15-May	Cholesterol
Y	15	None	8	0.6	26-Jul-17	Mixed
Y	21	None	9	0.3	19-Nov-16	Mixed
Y	17	None	8	0.6	20-Aug-17	Mixed
Y	43	None	7	0.6	4-Jul	
Y	19	None	8	0.6	28-Feb-18	Pigmented